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Balloon-Expandable Versus Self-Expanding Valves in Transcatheter Aortic Valve Replacement for Patients with Left Ventricular Systolic Dysfunction

Sol Ventrikül Sistolik Disfonksiyonu Olan ve Transkateter Aort Kapak Replasmanı Yapılan Hastalarda Balon-Expandabl ve Self-Expandabl Kapakların Karşılaştırılması

ORIGINAL ARTICLE
KLİNİK ÇALIŞMA

ABSTRACT

Objective: Patients with severe aortic stenosis (AS) and left ventricular systolic dysfunction (LVSD) represent a particularly fragile subgroup undergoing transcatheter aortic valve replacement (TAVR). Comparative outcome data for balloon-expandable valves (BEV) and self-expanding valves (SEV) in this population remain scarce.

Method: This retrospective single-center study evaluated 246 consecutive subjects with left ventricular ejection fraction (LVEF) < 50% who underwent transfemoral TAVR between January 2015 and June 2025. Clinical, echocardiographic, and procedural characteristics were compared between BEV (n = 96) and SEV (n = 150) recipients. Long-term all-cause mortality served as the primary endpoint.

Results: Individuals treated with BEV were older (78.8 ± 7.9 vs. 75.7 ± 9.8 years; P = 0.019) and demonstrated higher EuroSCORE II (European System for Cardiac Operative Risk Evaluation II) values (24.9 ± 6.2% vs. 22.2 ± 15.8%; P = 0.01). Periprocedural and in-hospital clinical outcomes, including mortality, vascular complications, and pacemaker requirement, were comparable between groups. SEV implantation yielded lower post-procedural transvalvular gradients (mean 7.8 ± 4.0 mmHg vs. 9.6 ± 4.1 mmHg; P = 0.001). Although crude mortality was observed more frequently among BEV patients (50.0% vs. 36.0%; P = 0.041), Kaplan–Meier survival curves showed no survival difference (log-rank P = 0.92). In multivariable Cox regression, predictors of long-term mortality included older age (hazard ratio [HR] 1.05; P = 0.007), chronic obstructive pulmonary disease (COPD) (HR: 2.64; P < 0.001), coronary artery disease (HR: 2.08; P = 0.018), lower serum albumin (HR: 0.63; P = 0.011), and lower hemoglobin (HR: 0.84; P = 0.023); valve type was not predictive.

Conclusion: In patients with LVSD undergoing TAVR, BEV and SEV provided comparable procedural and long-term outcomes. Although SEV yielded lower postoperative gradients, valve type did not affect survival. Future studies with larger samples and higher use of new-generation devices are warranted to refine valve selection in this high-risk group.

Keywords: Balloon-expandable valve, low-flow low-gradient aortic stenosis, self-expanding valve, transcatheter aortic valve implantation, transcatheter aortic valve replacement

ÖZET

Amaç: Sol ventrikül sistolik disfonksiyonu (LVSD) bulunan hastalar, transkateter aort kapak replasmanı (TAVR) uygulamalarında yüksek riskli bir alt grubu oluşturur. Bu hasta grubunda balon-expandabl (BEV) ve self-expandabl (SEV) kapakların karşılaştırmalı verileri sınırlıdır.

Yöntem: Bu çalışmada, Ocak 2015 – Haziran 2025 tarihleri arasında ejeksiyon fraksiyonu < %50 olan ve transfemoral yolla TAVR uygulanan 246 ardışık hasta retrospektif olarak analiz edilmiştir. Klinik, ekokardiyografik ve prosedürel değişkenler BEV (n = 96) ve SEV (n = 150) grupları arasında karşılaştırılmıştır. Birincil sonlanım noktası uzun dönem tüm nedenlere bağlı mortalitedir.

Bulgular: BEV grubundaki hastalar daha yaşlıydı (78.8 ± 7.9 vs. 75.7 ± 9.8, P = 0.019) ve EuroSCORE II değerleri daha yüksekti (%24,9 ± 6,2 vs. %22,2 ± 15,8; P = 0,01). Perioperatif ve hastane içi komplikasyonlar, majör vasküler olaylar ve kalıcı pacemaker ihtiyacı iki grup arasında benzerdi. SEV grubunda postoperatif transvalvüler gradiyentler daha düşüktü (ortalama 7,8 ± 4,0 mmHg vs 9,6 ± 4,1 mmHg; P = 0,001). Uzun dönem mortalite BEV grubunda daha yüksek izlense de (%50,0 vs %36,0; P = 0,041), Kaplan–Meier analizi fark göstermedi (log-rank P = 0,92). Çok değişkenli Cox regresyon analizinde ileri yaş (HR: 1,05; P = 0,007), KOAH varlığı

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(HR: 2,64; P< 0,001), koroner arter hastalığı (HR: 2,08; P = 0,018), düşük albümin (HR: 0,63; P = 0,011) ve düşük hemoglobin (HR: 0,84; P = 0,023) uzun dönem mortalitenin bağımsız belirleyicileri olarak bulundu; kapak tipi belirleyici olarak saptanmadı.

Sonuç: LVSD hastalarında TAVR sonrası BEV ve SEV kapaklar benzer işlem başarısı ve uzun dönem sonuçlar göstermektedir. SEV kapaklar daha düşük postoperatif gradiyentler sağlasa da, kapak tipi sağkalımı etkilememektedir. Yeni nesil cihazların daha yüksek oranda kullanıldığı ileri prospektif çalışmalara ihtiyaç bulunmaktadır.

Anahtar Kelimeler: Balon-expandabl kapak, düşük-akım düşük-gradiyentli aort stenozu, self-expandabl kapak, transkateter aort kapak implantasyonu, transkateter aort kapak replasmanı

Transcatheter aortic valve replacement (TAVR) has become a well-established treatment option across the entire spectrum of operative risk, supported by multiple randomized and registry studies demonstrating comparable or superior outcomes in appropriately selected patients.[1–3] Among individuals with left ventricular systolic dysfunction (LVSD), particularly those with a low-flow, low-gradient (LFLG) pattern, procedural risk and long-term mortality remain substantially higher than in patients with preserved systolic function.[4–11] Nevertheless, TAVR often leads to meaningful recovery in ventricular performance and improvement in survival among patients with reduced ejection fraction.[12–14] In the report by Ludwig et al.,[15] TAVR was associated with better two-year survival than conservative medical treatment, even in patients with moderate aortic stenosis and LVSD, emphasizing its potential benefit in this high-risk population.

Balloon-expandable (BEV) and self-expanding (SEV) valves differ in design, deployment mechanics, and hemodynamic performance, which may translate into distinct procedural and clinical profiles. BEVs are generally associated with lower rates of new pacemaker implantation, moderate or severe paravalvular regurgitation (PVR), and device embolization.[16–19] In contrast, SEVs generally provide lower transvalvular gradients (reflecting superior hemodynamics due to their supra-annular design) and reduce the need for rapid pacing during deployment.[16–21] Previous studies have consistently demonstrated comparable short- and long-term mortality rates for both valve types in the overall TAVR population.[16–21] However, complications such as high-grade atrioventricular block, moderate or severe PVR, or device embolization may be less well tolerated in patients with LVSD, whereas the hemodynamic advantages of SEVs could have greater long-term relevance in this group. Despite broad experience with both platforms in general TAVR practice, evidence focusing specifically on patients with reduced ejection fraction remains scarce. Given their heightened susceptibility to adverse hemodynamic events, a clear understanding of device-related outcomes in this subset is essential. Given these mechanistic differences, valve selection may have greater clinical relevance in patients with left ventricular (LV) systolic dysfunction, who possess limited hemodynamic reserve and may be less able to tolerate complications such as paravalvular regurgitation, conduction disturbances requiring new pacemaker implantation, suboptimal valve positioning, or higher residual gradients. These device-specific features could theoretically influence myocardial afterload, ventricular recovery, and ultimately long-term mortality in this vulnerable subgroup. Therefore, this study aims to provide real-world evidence comparing the clinical outcomes of patients with LVSD who underwent TAVR for severe aortic stenosis.

ABBREVIATIONS

AKI	Acute kidney injury
AS	Aortic stenosis
BEV	Balloon-expandable valves
CAD	Coronary artery disease
CKD	Chronic kidney disease
COPD	Chronic obstructive pulmonary disease
CT	Computed tomography
ECMO	Extracorporeal membrane oxygenation
EF	Ejection fraction
IABP	Intra-aortic balloon pump
LFLG	Low-flow, low-gradient
LVEF	Left ventricular ejection fraction
LVSD	Left ventricular systolic dysfunction
MI	Myocardial infarction
PASP	Pulmonary artery systolic pressure
PCI	Percutaneous coronary intervention
PVR	Paravalvular regurgitation
SAPT	Single antiplatelet therapy
SEV	Self-expanding valves
TAPSE	Tricuspid annular plane systolic excursion
TAVR	Transcatheter aortic valve replacement
VARC-3	Valve Academic Research Consortium-3

Materials and Methods

Study Population

This single-center retrospective analysis included 246 consecutive patients treated with transfemoral TAVR for severe symptomatic native aortic stenosis (AS) between January 2015 and June 2025. Patient data, including baseline clinical characteristics, comorbidities, regular medications, laboratory values, echocardiographic parameters, angiographic and procedural details, and follow-up, were retrieved from the hospital information system and patient records and then anonymized for analysis.

Eligibility required a left-ventricular ejection fraction (LVEF) below 50% prior to the procedure. Laboratory values and echocardiographic parameters were obtained at admission, and all surviving patients underwent follow-up echocardiography at 6 months after TAVR. All echocardiographic evaluations were carried out using a Vivid E95 system (GE Vingmed Ultrasound, Milwaukee, WI, USA). Measurements were performed in accordance with the European Association of Cardiovascular Imaging and the American Society of Echocardiography.[22] LVEF was quantified by an experienced echocardiographer using the biplane Simpson's method.

Exclusion criteria were as follows:

- Valve-in-valve TAVR (n = 8)
- TAVR performed for isolated severe aortic insufficiency (n = 5)
- Missing data (n = 11)
- Active malignancy (n = 1)
- Severe anemia (hemoglobin < 8 mg/dL) (n = 2)
- End-stage renal failure (estimated glomerular filtration rate < 30 mL/min/1.73 m^2 or chronic dialysis) (n = 8)
- Non-transfemoral access (n = 14).

After applying these strict exclusion criteria, the remaining 246 patients constituted the final study population. The study complied with the ethical standards of the Declaration of Helsinki and received approval from Istanbul Medipol University Non-Interventional Clinical Research Ethics Committee (Approval Number: 1150, Date: 25.09.2025). All participants provided written informed consent upon hospital admission and before undergoing any invasive procedures, including permission for the scientific use of their data.

Procedural Information

All participants underwent diagnostic coronary angiography before TAVR, typically two days prior to valve implantation. Revascularization decisions were made jointly by the interventional team based on coronary anatomy and clinical presentation. A luminal narrowing ≥ 90% in vessels with a diameter ≥ 2.5 mm was considered significant and managed with percutaneous coronary intervention (PCI) when appropriate. Standard dual loading with clopidogrel 600 mg and aspirin 300 mg preceded PCI. The SYNTAX I score (Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery score) was calculated to quantify the anatomical complexity and severity of coronary artery disease (CAD).

Per institutional protocol, patients without an indication for long-term anticoagulation received dual antiplatelet therapy (DAPT) with aspirin 100 mg and clopidogrel 75 mg daily for three months, followed by lifelong single antiplatelet therapy (SAPT). In patients requiring oral anticoagulation, no additional antiplatelet therapy was given unless recent PCI had been performed. For patients who underwent PCI before TAVR, DAPT was continued for six months and then transitioned to SAPT in the absence of anticoagulation. Patients who required both TAVR and PCI and had an indication for oral anticoagulation received triple therapy (DAPT plus anticoagulation) for one week, followed by SAPT plus anticoagulation for up to six months post-PCI, and anticoagulation alone thereafter. All coronary angiography and PCI procedures were performed via radial arterial access.

All TAVR procedures were performed via transfemoral access. The choice of femoral access site was guided by pre-procedural computed tomography (CT) evaluation. Vascular access was obtained under combined fluoroscopic and ultrasound guidance. A 6F pigtail catheter was used for contrast injections during valve deployment. A temporary pacing lead was placed via the femoral vein in all patients before valve implantation. Standardized CT analyses were performed using the 3mensio Structural Heart software (Pie Medical Imaging, Maastricht, the Netherlands), and prosthesis sizes were determined based on these measurements. The decision regarding valve type—BEV or SEV—was made by the primary interventional cardiologist after comprehensive case evaluation. As this was a retrospective study, detailed criteria guiding the choice between BEV and SEV were not consistently documented, and device selection was primarily based on operator preference. Vascular closure was achieved with Perclose ProGlide (Abbott Vascular, Santa Clara, CA) or Angio-Seal (Terumo Corp., Tokyo, Japan) systems when feasible. Surgical repair or covered stent implantation was performed if closure failed or major vascular injury occurred.

Definitions and Outcomes

Study outcomes were determined according to the standardized definitions proposed by the Valve Academic Research Consortium-3 (VARC-3).[23] The primary endpoint of the study was all-cause mortality during long-term follow-up. Secondary clinical outcomes included in-hospital death and periprocedural events such as cardiac tamponade or rupture, myocardial infarction (MI), coronary obstruction, aortic dissection or rupture, stroke, permanent pacemaker requirement, device embolization, acute kidney injury (AKI), vascular complications, bleeding events, need for intra-aortic balloon pump (IABP) or extracorporeal membrane oxygenation (ECMO), technical success, and device success. According to VARC-3 definitions, bleeding events classified as Type 2, 3, or 4 were considered major bleeding, whereas Type 1 events were considered minor bleeding.

Major vascular complications included any of the following events: aortic dissection or rupture; vascular injury, distal embolization, closure device failure, or unplanned endovascular or surgical procedures leading to mortality, major bleeding, limb or visceral ischemia, or irreversible neurologic disability. Minor vascular complications included distal embolization, vascular injury, closure device failure, or unplanned endovascular or surgical intervention not resulting in VARC type ≥ 2 bleeding, death, irreversible neurologic impairment, or limb or visceral ischemia.[23] Definitions for MI and AKI were also based on VARC-3 recommendations.

Technical success was defined as fulfillment of all the following criteria at completion of the TAVR procedure: absence of mortality; successful vascular access; successful delivery and retrieval of the delivery system; correct positioning of the valve; and absence of the need for surgery or intervention due to device-related, major vascular, or cardiac structural complications.

Device success at 30 days post-procedure was defined as the presence of technical success; absence of mortality; absence of the need for surgery or intervention due to device-, major vascular-, access-related, or cardiac structural complications; and adequate valve performance, defined as peak aortic velocity < 3 m/s, mean aortic gradient < 20 mmHg, Doppler velocity index ≥ 0.25, and less than moderate aortic regurgitation.

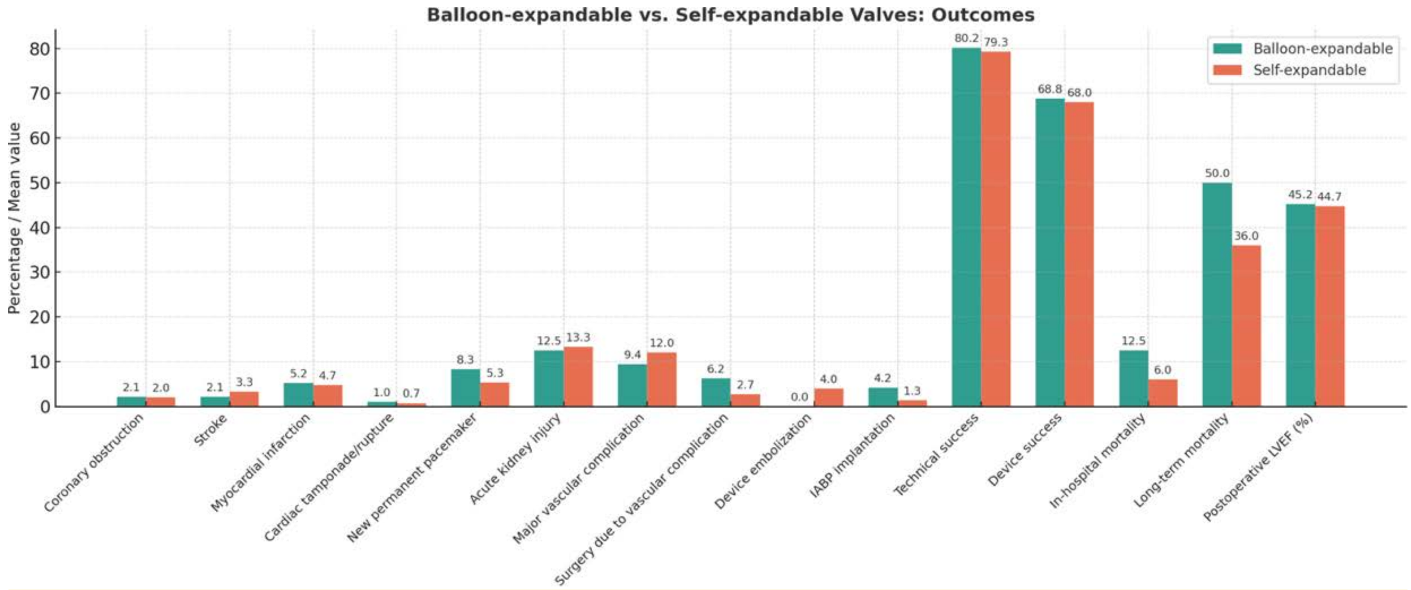

Figure 1. Comparison of perioperative and long-term outcomes between balloon-expandable valve (BEV) and self-expanding valve (SEV) groups.

All-cause mortality, the primary endpoint, was determined using a combination of the hospital electronic medical record system and direct telephone contact with patients' first-degree relatives when necessary. Periprocedural and in-hospital outcomes were obtained from the hospital information system, operative reports, and discharge summaries. Long-term clinical events were verified through scheduled outpatient clinic visits and review of electronic medical records.

Statistical Analysis

Continuous variables were tested for normality using visual histograms and the Kolmogorov–Smirnov test. Data with a normal distribution were compared using the t-test, whereas non-normally distributed variables were analyzed with the Mann–Whitney U test. Categorical variables were analyzed using the chi-square or Fisher's exact test, as appropriate. Results were expressed as mean ± standard deviation for normally distributed data and as median (interquartile range) otherwise; categorical variables were presented as counts and percentages.

Kaplan–Meier survival curves and the log-rank test were used to evaluate long-term all-cause mortality between valve groups. Predictors of mortality were assessed using Cox proportional hazards regression, employing a stepwise method for univariate and multivariate modeling. Results were expressed as hazard ratios (HRs) with 95% confidence intervals (CIs).

All analyses were performed using Python 3.11 (Python Software Foundation, Wilmington, DE, USA). A two-sided $P < 0.05$ denoted statistical significance.

Results

A total of 246 patients with LVEF < 50% underwent transfemoral TAVR and were included in the final analysis. Of these, 96 (39%) received balloon-expandable valves and 150 (61%) received self-expanding valves. Patients in the BEV group were older (78.8 ± 7.9 vs. 75.7 ± 9.8 years, P = 0.019) and had a lower body mass index (26.0 ± 3.2 kg/m² vs. 27.8 ± 4.4 kg/m², P = 0.001). The EuroSCORE II (European System for Cardiac Operative Risk Evaluation II) was also higher in the BEV group (24.9 ± 6.2% vs. 22.2 ± 15.8%, P = 0.01). Comorbidities and medical therapy were generally comparable between groups, except for more frequent use of sodium–glucose cotransporter-2 inhibitors in the SEV group (34.0% vs. 12.5%, P < 0.001). Laboratory values did differ between groups. Detailed baseline clinical characteristics, comorbidities, follow-up medications, and laboratory values are presented in Table 1.

Among BEV recipients, 15 patients (15.6%) received newer-generation Myval™ (Meril Life Sciences Pvt. Ltd., Vapi, India), while the remainder received older-generation SAPIEN XT™ valves (Edwards Lifesciences LLC, Irvine, CA, USA). In the SEV group, 21 patients (14.0%) received newer-generation Evolut PRO™ or Evolut PRO+™ valves (Medtronic, Minneapolis, MN, USA), and the remaining patients received first-generation CoreValve™ prostheses (Medtronic, Minneapolis, MN, USA).

Preoperative echocardiographic characteristics, including LVEF, aortic maximum velocity, maximum and mean aortic gradients, aortic valve area, ascending aorta diameter, tricuspid annular plane systolic excursion (TAPSE), left atrial (LA) diameter, and pulmonary artery systolic pressure (PASP), were comparable between groups (Table 2). However, the SEV group included a higher proportion of patients with low-flow, low-gradient severe aortic stenosis (30.7% vs. 17.7%, P = 0.034) and had narrower aortic roots (2.8 ± 0.4 cm vs. 2.9 ± 2.3 cm, P = 0.011).

SYNTAX I scores derived from preprocedural coronary angiography were comparable between groups (14.7 ± 10.0 vs. 12.3 ± 11.3, P = 0.076), as were rates of PCI prior to TAVR (16.7% vs. 18.7%, P = 0.720). The SEV group required smaller sheath sizes for valve delivery (14.8 ± 1.6 mm vs. 17.5 ± 2.3 mm, P < 0.001). While rates of pre-dilation were similar (30.2% vs. 33.3%, P = 0.710), post-dilation was performed

Table 1. Comparison of baseline clinical characteristics, comorbidities, follow-up medications, and laboratory parameters between self-expanding and balloon-expandable valve groups

Variables	Balloon-expandable group (n = 96)	Self-expanding group (n = 150)	*P*
Baseline clinical characteristics and comorbidities			
Age (years)	78.8 ± 7.9	75.7 ± 9.8	0.019
Male sex	55 (57.3%)	91 (60.7%)	0.599
Body mass index (kg/m^2)	26.0 ± 3.2	27.8 ± 4.4	0.001
NYHA class	NYHA II: 25 (26.0%)	NYHA II: 27 (18.0%)	0.301
	NYHA II: 58 (60.4%)	NYHA III: 103 (68.7%)	
	NYHA IV: 13 (13.5%)	NYHA IV: 20 (13.3%)	
EuroSCORE II, (%)	24.9 ± 6.2	22.2 ± 15.8	0.01
Hypertension	86 (89.6%)	123 (82.0%)	0.105
Diabetes mellitus	40 (41.7%)	76 (50.7%)	0.168
Atrial fibrillation	33 (34.4%)	59 (39.3%)	0.433
COPD	52 (54.2%)	64 (42.7%)	0.078
Previous stroke	10 (10.4%)	6 (4.0%)	0.046
Chronic kidney disease	47 (49.0%)	68 (45.3%)	0.578
Coronary artery disease	68 (70.8%)	106 (70.7%)	0.978
Previous CABG	20 (20.8%)	31 (20.7%)	0.975
Peripheral arterial disease	5 (5.2%)	14 (9.3%)	0.237
Pre-operative pacemaker	10 (10.4%)	10 (6.7%)	0.294
Follow-up medications			
ACEi/ARB use	53 (55.2%)	83 (55.3%)	0.985
Beta-blocker use	84 (87.5%)	135 (90.0%)	0.541
SGLT-2i use	12 (12.5%)	51 (34.0%)	<0.001
Anticoagulation	25 (26.0%)	53 (35.3%)	0.127
Statin use	52 (54.2%)	77 (51.3%)	0.664
Insulin use	11 (11.5%)	23 (15.3%)	0.390
MRA use	20 (20.8%)	42 (28.0%)	0.207
ARNI use	2 (2.1%)	11 (7.3%)	0.073
Laboratory parameters			
Hemoglobin (g/dL)	11.36 ± 1.55	11.53 ± 1.86	0.446
WBC (cells/L)	(7.98 ± 3.03) × 10^3	8.13 ± 2.71 × 10^3	0.705
Platelets (cells/mcL)	(228.97 ± 89.96) × 10^3	(215.11 ± 65.21) × 10^3	0.197
Creatinine (mg/dL)	1.31 ± 0.75	1.36 ± 1.33	0.717
Glomerular filtration rate (mL/min/1.73 m^2)	65.09 ± 23.88	64.77 ± 25.72	0.919
AST (IU/L)	18.65 ± 11.33	22.87 ± 30.88	0.148
Albumin (g/dL)	4.44 ± 0.89	4.34 ± 0.71	0.444
Sodium (mEq/L)	137.22 ± 3.71	136.72 ± 11.78	0.638
Potassium (mEq/L)	4.43 ± 0.53	4.40 ± 0.50	0.762
TSH (mIU/L)	2.23 ± 2.24	2.43 ± 3.08	0.626
Total cholesterol (mg/dL)	205.02 ± 51.66	197.40 ± 47.73	0.339
LDL cholesterol (mg/dL)	125.81 ± 40.08	122.12 ± 43.03	0.543
HDL cholesterol (mg/dL)	43.06 ± 15.65	39.66 ± 10.06	0.123
Triglycerides (mg/dL)	149.72 ± 48.26	157.80 ± 52.23	0.306

ACEi, Angiotensin-converting enzyme inhibitor; ARB, Angiotensin II receptor blocker; ARNI, Angiotensin receptor–neprilysin inhibitor; AST, Aspartate aminotransferase; CABG, Coronary artery bypass graft surgery; COPD, Chronic obstructive pulmonary disease; HDL, High-density lipoprotein; LDL, Low-density lipoprotein; MRA, Mineralocorticoid receptor antagonist; NYHA, New York Heart Association; SGLT-2i, Sodium–glucose cotransporter-2 inhibitor; TSH, Thyroid-stimulating hormone; WBC, White blood cell.

Table 2. Comparison of pre-operative echocardiographic parameters and angiographic characteristics between self-expanding and balloon-expandable valve groups

Variables	Balloon-expandable group (n = 96)	Self-expanding group (n = 150)	*P*
Preoperative echocardiographic parameters			
LVEF (%)	40.9 ± 9.4	40.2 ± 9.0	0.454
Aortic maximum velocity (m/s)	4.0 ± 0.7	3.9 ± 0.7	0.259
Maximum aortic gradient (mmHg)	68.2 ± 23.2	64.4 ± 22.5	0.150
Mean aortic gradient (mmHg)	44.0 ± 15.8	40.6 ± 14.7	0.085
Aortic valve area (cm^2)	0.7 ± 0.2	0.7 ± 0.2	0.738
Aortic root diameter (cm)	2.9 ± 2.3	2.8 ± 0.4	0.011
Ascending aorta diameter (cm)	3.8 ± 0.5	3.8 ± 0.4	0.890
TAPSE (cm)	1.8 ± 0.3	1.9 ± 0.3	0.211
Left atrial diameter (cm)	4.5 ± 0.6	4.5 ± 0.6	0.251
PASP (mmHg)	46.3 ± 11.8	46.7 ± 11.1	0.845
Low-flow, low-gradient severe AS	17 (17.7%)	46 (30.7%)	0.034
Aortic regurgitation	Absent: 8 (8.3%)	Absent: 34 (22.2%)	0.020
	Mild: 40 (41.7%)	Mild: 47 (31.5%)	
	Moderate: 28 (29.2%)	Moderate: 46 (30.9%)	
	Severe 20 (20.8%)	Severe: 23 (15.4%)	
Tricuspid regurgitation	Mild: 13 (13.5%)	Mild: 32 (20.8%)	0.095
	Moderate: 41 (42.7%)	Moderate: 71 (47.7%)	
	Severe: 42 (43.8%)	Severe: 47 (31.5%)	
Mitral regurgitation	Absent: 1 (1.0%)	Absent: 7 (4.0%)	0.031
	Mild: 23 (24.0%)	Mild: 41 (27.5%)	
	Moderate: 32 (33.3%)	Moderate: 64 (43.0%)	
	Severe: 40 (41.7%)	Severe: 38 (25.5%)	
Angiographic and interventional characteristics			
SYNTAX I score	14.7 ± 10.0	12.3 ± 11.3	0.076
Sheath size (mm)	17.5 ± 2.3	14.8 ± 1.6	<0.001
Pre-dilation	29 (30.2%)	50 (33.3%)	0.710
Post-dilation	6 (6.2%)	58 (38.7%)	<0.001
Valve size (mm)	26.7 ± 2.5	29.7 ± 3.5	<0.001
PCI during hospitalization	16 (16.7%)	28 (18.7%)	0.720

AS, Aortic stenosis; LVEF, Left ventricular ejection fraction; PASP, Pulmonary artery systolic pressure; PCI, Percutaneous coronary intervention; TAPSE, Tricuspid annular plane systolic excursion.

more frequently in the SEV group (38.7% vs. 6.2%, P < 0.001). Mean prosthesis diameter was larger in the SEV group (29.7 ± 3.5 mm vs. 26.7 ± 2.5 mm, P < 0.001).

The median follow-up duration for the overall cohort was 1,037 days (interquartile range (IQR): 370–1,629 days). The BEV group had a numerically longer follow-up period compared with the SEV group (1,160 [352–2,414] days vs. 962 [432–1,449] days, P = 0.09). Periprocedural and in-hospital outcomes, including coronary obstruction, stroke, myocardial infarction, cardiac tamponade or rupture, aortic dissection, permanent pacemaker implantation, acute kidney injury, major vascular complications, and in-hospital death, were comparable between groups (Table 3, Figure 1). Technical success (80.2% vs. 79.3%, P = 0.997) and device success (68.8% vs. 68.0%, P = 1.000) were also similar.

Postoperative six-month echocardiographic follow-up demonstrated comparable LVEF, PASP, LVEF recovery, left atrial diameter, and rates of moderate or severe PVR between the BEV and SEV groups (Table 3, Figure 1). However, the SEV group exhibited significantly lower postoperative transvalvular gradients, both maximal (14.3 ± 6.8 mmHg vs. 17.2 ± 7.0 mmHg, P = 0.001) and mean (7.8 ± 4.0 mmHg vs. 9.6 ± 4.1 mmHg, P = 0.001).

Long-term mortality occurred more frequently in the BEV group (50.0% vs. 36.0%, P = 0.041); however, Kaplan–Meier survival curves demonstrated no statistically significant difference between the valve groups (log-rank P = 0.92) (Figure 2).

To identify predictors of long-term all-cause mortality, stepwise univariate and multivariate Cox regression analyses

Table 3. Comparison of follow-up data and outcomes between self-expanding and balloon-expandable valve groups

Variables	Balloon-expandable group (n = 96)	Self-expanding group (n = 150)	*P*
Follow-up duration (days)	1160 (352–2414) days	962 (432–1449) days	0.09
Perioperative complications and outcomes			
Coronary obstruction	2 (2.1%)	3 (2.0%)	1.0
Stroke	2 (2.1%)	5 (3.3%)	0.855
Myocardial infarction	5 (5.2%)	7 (4.7%)	0.870
Cardiac tamponade/rupture	1 (1.0%)	1 (0.7%)	1.0
Aortic dissection	0 (0.0%)	0 (0.0%)	1.0
New permanent pacemaker	8 (8.3%)	8 (5.3%)	0.506
Acute kidney injury	12 (12.5%)	20 (13.3%)	1.0
Major vascular complication	9 (9.4%)	18 (12.0%)	0.665
Minor vascular complication	14 (14.6%)	27 (18.0%)	0.599
Surgery due to vascular complication	6 (6.2%)	4 (2.7%)	0.290
Major bleeding	9 (9.4%)	22 (14.7%)	0.306
Minor bleeding	14 (14.6%)	27 (18.0%)	0.599
Device embolization	0 (0.0%)	6 (4.0%)	0.119
IABP implantation	4 (4.2%)	2 (1.3%)	0.326
ECMO use	1 (1.0%)	0 (0.0%)	0.822
Hospitalization duration (days)	5.4 ± 3.0	5.9 ± 4.8	0.979
Technical success	77 (80.2%)	119 (79.3%)	0.997
Device success	66 (68.8%)	102 (68.0%)	1.0
In-hospital mortality	12 (12.5%)	9 (6.0%)	0.122
Long-term outcomes and control echocardiography at 6 months after TAVR			
Long-term mortality	48 (50.0%)	54 (36.0%)	0.041
Postoperative LVEF (%)	45.2 ± 10.6	44.7 ± 11.1	0.763
Postoperative LVEF change (%)	3.92 ± 5.60	4.16 ± 6.71	0.593
Moderate or severe PVL	9 (9.4%)	17 (11.3%)	0.889
Postoperative maximum aortic gradient (mmHg)	17.2 ± 7.0	14.3 ± 6.8	0.001
Postoperative mean aortic gradient (mmHg)	9.6 ± 4.1	7.8 ± 4.0	0.001
Postoperative PASP (mmHg)	41.6 ± 11.1	39.3 ± 12.0	0.136
Postoperative left atrial diameter (cm)	4.5 ± 0.5	4.5 ± 0.6	0.123

ECMO, Extracorporeal membrane oxygenation; IABP, Intra-aortic balloon pump; LVEF, Left ventricular ejection fraction; PASP, Pulmonary artery systolic pressure; PVL, Paravalvular leak.

were performed. Baseline clinical features, laboratory values, echocardiographic parameters, medications, and angiographic and procedural variables were included in the initial univariate analysis (Table 4). In univariate analysis, the following parameters predicted long-term mortality: age (HR: 1.05, 95% CI: 1.03–1.08, P < 0.001), chronic obstructive pulmonary disease (COPD) (HR: 1.72, 95% CI: 1.16–2.55, P = 0.007), chronic kidney disease (CKD) (HR: 1.68, 95% CI: 1.14–2.49, P = 0.009), lower preoperative aortic gradients, perioperative acute kidney injury (HR: 2.65, 95% CI: 1.62–4.33, P < 0.001), higher serum sodium (HR: 1.07, 95% CI: 1.02–1.13, P = 0.013), presence of coronary artery disease (HR: 1.70, 95% CI: 1.07–2.72, P = 0.025), lower serum albumin (HR: 0.74, 95% CI: 0.56–0.97, P = 0.032), lower postoperative LVEF (HR: 0.98, 95% CI: 0.96–1.00, P = 0.032), LFLG aortic stenosis (HR: 1.61, 95% CI: 1.03–2.53, P = 0.037), perioperative stroke (HR: 2.77, 95% CI: 1.02–7.56, P = 0.046), lower preoperative hemoglobin (HR: 0.89, 95% CI: 0.79–1.00, P = 0.047), and perioperative minor bleeding (HR: 1.67, 95% CI: 1.04–2.68, P = 0.034). Valve type (BEV vs. SEV) was not associated with long-term mortality.

Significant variables identified in univariate analysis, except for preoperative maximum aortic gradient (to avoid collinearity with mean gradient), were entered into the multivariate model. In multivariate Cox regression, COPD (HR: 2.64, 95% CI: 1.54–4.52, P < 0.001), age (HR: 1.05, 95% CI: 1.01–1.08, P = 0.007), lower preoperative mean aortic gradient (HR: 0.97, 95% CI: 0.94–1.00, P = 0.034), coronary artery disease (HR: 2.08, 95% CI: 1.13–3.81, P = 0.018), lower serum albumin (HR: 0.63, 95% CI: 0.44–0.90, P = 0.011), and lower preoperative hemoglobin (HR: 0.84, 95% CI: 0.72–0.98, P = 0.023) remained independent predictors of long-term mortality (Table 4, Figure 3).

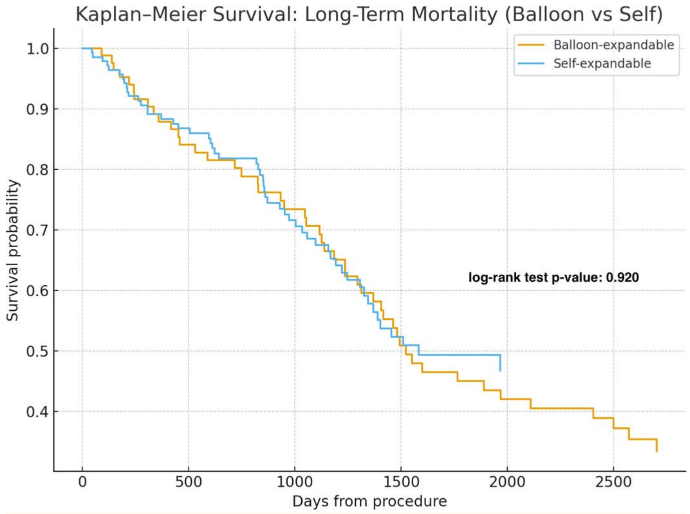

Figure 2. Kaplan-Meier curves for long-term all-cause mortality in patients undergoing transcatheter aortic valve replacement (TAVR) with balloon-expandable valves (BEV) and self-expanding valves (SEV).

In this cohort of patients with severely reduced left ventricular systolic function (LVEF < 40%) undergoing TAVR, baseline demographic and clinical characteristics were largely comparable between the balloon-expandable and self-expanding valve groups (Table 5). Age, sex distribution, comorbidities, and surgical risk scores did not differ significantly; however, patients treated with self-expanding valves had a higher body mass index (27.9 ± 3.93 kg/m^2 vs. 26.1 ± 3.20 kg/m^2, P = 0.014), a higher prevalence of SGLT-2 (sodium–glucose cotransporter-2) inhibitor use (47.4% vs. 17.5%, P = 0.003), and lower rates of prior stroke (1.3% vs. 15.0%, P = 0.006). Pre-procedural echocardiography demonstrated comparable LVEF, aortic gradients, aortic valve areas, and similar frequencies of low-flow, low-gradient severe aortic stenosis in both groups, although patients receiving balloon-expandable valves exhibited lower TAPSE values (1.66 ± 0.26 cm vs. 1.76 ± 0.21 cm, P = 0.015) and a higher prevalence of severe aortic regurgitation (30.0% vs. 10.5%, P = 0.017). Procedurally, balloon-expandable valves were associated with the use of larger sheath sizes (17.7 ± 2.20 Fr vs. 14.9 ± 1.23 Fr, P < 0.001) and smaller prosthesis diameters (27.3 ± 2.33 mm vs. 30.7 ± 3.23 mm, P < 0.001). Long-term follow-up was significantly longer in the balloon-expandable group (1575.5 [712.8–2740.3] vs. 999.0 [607.8–1406.0] days, P = 0.001). Periprocedural complication rates, including MI, stroke, acute kidney injury, vascular complications, and bleeding, were similar between groups. In-hospital mortality was higher in the balloon-expandable cohort (20.0% vs. 5.3%, P = 0.022), whereas long-term mortality did not differ significantly (47.5% vs. 39.5%, P = 0.526). Device and technical success rates were comparable between the two valve types (Table 5). Kaplan-Meier analysis also showed comparable survival probabilities between the two groups, with a log-rank p-value of 0.453 (Figure 4).

In the multivariate Cox regression analysis model for the prediction of long-term mortality in patients with advanced heart failure (LVEF < 40%) and severe aortic stenosis, COPD (HR: 1.91; 95% CI: 1.03–3.57; P = 0.041) and mean postoperative aortic gradient (HR: 0.97 per 1 mmHg; 95% CI: 0.94–0.99; P = 0.011) emerged as independent predictors (Table 6). Age, coronary artery disease, and valve type (BEV vs. SEV) were not significantly associated with long-term mortality (Table 6).

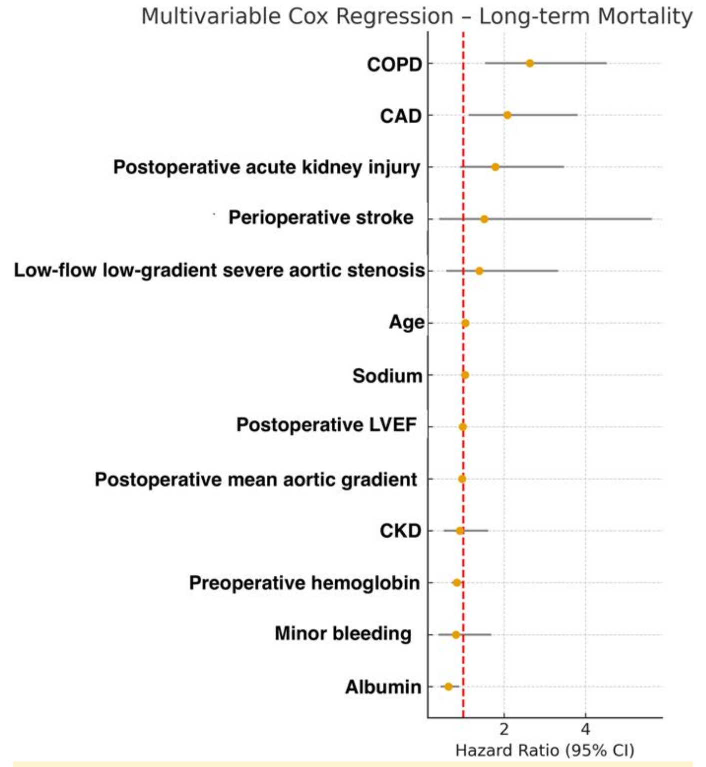

Figure 3. Forest plot showing independent predictors of long-term all-cause mortality following transcatheter aortic valve replacement (TAVR) in patients with reduced left ventricular ejection fraction.

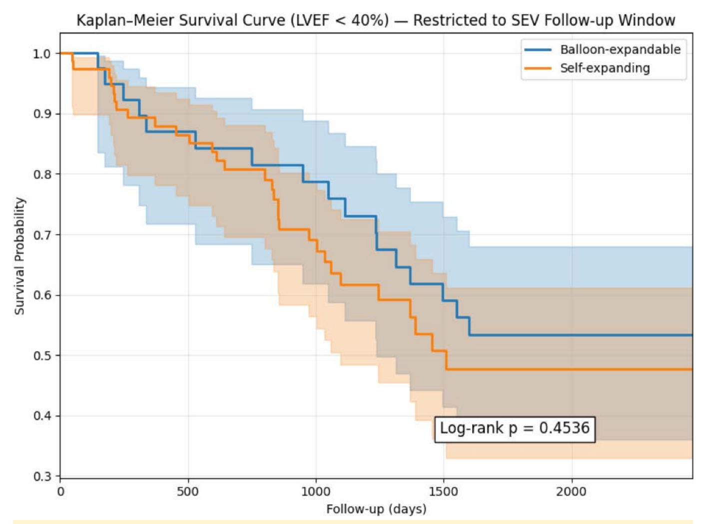

Figure 4. Kaplan-Meier survival curves in advanced heart failure patients (left ventricular ejection fraction [LVEF] < 40%) undergoing transcatheter aortic valve replacement (TAVR) with balloon-expandable valves (BEV) and self-expanding valves (SEV).

Table 4. Univariate and multivariate Cox regression analyses for the prediction of long-term mortality

Variables	Univariate Cox Regression Analysis			Multivariate Cox Regression Analysis		
	HR	95% CI	*P*	HR	95% CI	*P*
Age (per 1 year)	1.05	1.03-1.08	**<0.001**	1.05	1.01-1.08	**0.007**
Male sex	0.99	0.67-1.47	0.951			
BEV vs. SEV	0.92	0.62-1.37	0.690			
COPD	1.72	1.16-2.55	**0.007**	2.64	1.54-4.52	**<0.001**
Chronic kidney disease	1.68	1.14-2.49	**0.009**	0.91	0.52-1.61	0.755
Preoperative maximum aortic gradient (per 1 mmHg)	0.99	0.98-1.00	**0.006**			
Preoperative mean aortic gradient (per 1 mmHg)	0.98	0.96-0.99	**0.002**	0.97	0.94-1.00	**0.034**
Perioperative AKI	2.65	1.62-4.33	**<0.001**	1.78	0.92-3.47	0.088
Sodium (per 1 mEq/L)	1.07	1.02-1.13	**0.013**	1.04	0.97-1.12	0.286
Coronary artery disease	1.70	1.07-2.72	**0.025**	2.08	1.13-3.81	**0.018**
Albumin (per 1 g/dL)	0.74	0.56-0.97	**0.032**	0.63	0.44-0.90	**0.011**
Postoperative LVEF (per 1%)	0.98	0.96-1.00	**0.032**	0.99	0.96-1.01	0.319
Low-flow, low-gradient aortic stenosis	1.61	1.03-2.53	**0.037**	1.39	0.58-3.33	0.456
Perioperative stroke	2.77	1.02-7.56	**0.046**	1.51	0.41-5.63	0.538
Preoperative hemoglobin (per 1 g/dL)	0.89	0.79-1.00	**0.047**	0.84	0.72-0.98	**0.023**
Perioperative minor bleeding	1.67	1.04-2.68	**0.034**	0.81	0.39-1.69	0.580
Total cholesterol (per 1 mg/dL)	1.00	0.99-1.00	0.073			
LDL cholesterol (per 1 mg/dL)	1.00	0.99-1.00	0.073			
Preoperative creatinine (per 1 mg/dL)	1.13	0.96-1.32	0.135			
Potassium (per 1 mEq/L)	0.76	0.50-1.13	0.176			
AST (per 1 IU/L)	1.01	1.00-1.01	0.190			
TSH (per 1 mIU/L)	0.93	0.83-1.04	0.195			
Body mass index (per 1 kg/m2)	0.96	0.91-1.01	0.079			
NYHA class III-IV	1.39	0.95-2.04	0.090			
Presence of device success	1.52	0.93-2.51	0.097			
Presence of technical success	1.33	0.71-2.50	0.366			
Preoperative LVEF (per 1%)	0.99	0.97-1.01	0.210			
Preoperative TAPSE (per 1 cm)	0.56	0.26-1.21	0.139			
Preoperative aortic root diameter (per 1 cm)	0.90	0.70-1.16	0.419			
Preoperative AVA (per 1 cm^2)	1.29	0.39-4.27	0.672			
Preoperative moderate or severe AR	0.99	0.81-1.21	0.927			
Postoperative moderate or severe MR	1.30	0.98-1.72	0.069			
Postoperative PASP (per 1 mmHg)	1.01	1.00-1.03	0.102			
Postoperative maximum aortic gradient (per 1 mmHg)	0.98	0.95-1.01	0.213			
Postoperative mean aortic gradient (per 1 mmHg)	0.95	0.90-1.01	0.105			
Beta-blocker use	0.64	0.36-1.12	0.117			
Insulin use	1.43	0.85-2.41	0.177			
SGLT-2i use	0.95	0.58-1.56	0.840			
Anticoagulation	1.06	0.69-1.61	0.793			
ARNI use	1.15	0.47-2.83	0.760			
MRA use	0.97	0.61-1.54	0.887			
ACEi/ARB use	1.12	0.76-1.66	0.574			
Statin use	0.88	0.60-1.30	0.535			
Diabetes mellitus	1.12	0.76-1.65	0.576			
Peripheral arterial disease	1.73	0.87-3.44	0.119			
CABG	1.14	0.72-1.82	0.573			
Hypertension	0.87	0.52-1.47	0.602			
Atrial fibrillation	1.10	0.74-1.65	0.636			
Previous stroke	1.14	0.53-2.47	0.733			
Postoperative pacemaker implantation	1.85	0.86-4.00	0.118			
Perioperative major vascular complication	0.69	0.32-1.49	0.348			
EuroSCORE II (per 1%)	1.01	1.00-1.03	0.141			
Moderate or severe PVL	0.73	0.35-1.51	0.396			
Major bleeding	0.83	0.43-1.60	0.576			
SYNTAX I score (per 1 increase)	1.00	0.97-1.02	0.841			

ACEi, Angiotensin-converting enzyme inhibitor; AKI: Acute kidney injury; AR, Aortic regurgitation; ARB, Angiotensin II receptor blocker; ARNI, Angiotensin receptor-neprilysin inhibitor; AST, Aspartate aminotransferase; AVA, Aortic valve area; BEV, Balloon-expandable valve; CABG, Coronary artery bypass graft surgery; CI, Confidence interval; COPD, Chronic obstructive pulmonary disease; HR, Hazard ratio; LDL, Low-density lipoprotein; LVEF, Left ventricular ejection fraction; MR, Mitral regurgitation; MRA, Mineralocorticoid receptor antagonist; NYHA, New York Heart Association; PASP, Pulmonary artery systolic pressure; PVL, Paravalvular leak; SEV, Self-expanding valve; SGLT-2i, Sodium–glucose cotransporter-2 inhibitor; TAPSE, Tricuspid annular plane systolic excursion; TSH, Thyroid-stimulating hormone.

Table 5. Comparison of balloon-expandable and self-expanding valves in patients with severely reduced ejection fraction (LVEF < 40%) and severe aortic stenosis

Variables	Balloon-expandable valve (n = 40)	Self-expanding valve (n = 76)	*P*
Baseline clinical characteristics and comorbidities			
Age (years)	77.9 ± 8.55	74.6 ± 11.50	0.176
Male sex	29 (72.5%)	53/76 (69.7%)	0.923
Body mass index (kg/m^2)	26.1 ± 3.20	27.9 ± 3.93	0.014
EuroSCORE II	25.5 ± 6.82	25.8 ± 17.75	0.298
Hypertension	35 (87.5%)	64 (84.2%)	0.841
Diabetes mellitus	20 (50.0%)	46 (60.5%)	0.373
Atrial fibrillation	14 (35.0%)	30 (39.5%)	0.787
COPD	24 (60.0%)	32 (42.1%)	0.101
Pre-operative pacemaker	4 (10.0%)	6 (7.9%)	0.735
Previous stroke	6 (15.0%)	1 (1.3%)	0.006
Chronic kidney disease	26 (65.0%)	40 (52.6%)	0.280
Coronary artery disease	26 (65.0%)	59 (77.6%)	0.215
Coronary artery bypass grafting	7 (17.5%)	20 (26.3%)	0.403
SYNTAX score	14.8 ± 10.40	13.4 ± 12.01	0.498
Peripheral arterial disease	3 (7.5%)	10 (13.2%)	0.538
Medications			
ACEi/ARB use	21 (52.5%)	41 (53.9%)	1.000
ARNI use	2 (5.0%)	9 (11.8%)	0.326
ß-blocker use	35 (87.5%)	72 (94.7%)	0.272
MRA use	12 (30.0%)	31 (40.8%)	0.347
SGLT-2 inhibitor use	7 (17.5%)	36 (47.4%)	0.003
Insulin use	6 (15.0%)	15 (19.7%)	0.707
Anticoagulation use	11 (27.5%)	27 (35.5%)	0.505
Statin use	22 (55.0%)	36 (47.4%)	0.558
Pre-operative echocardiographic data			
Low-flow, low-gradient severe aortic stenosis	17 (42.5%)	38 (50.0%)	0.566
Pre-operative LVEF (%)	31.0 ± 5.77	32.6 ± 5.77	0.131
Pre-operative maximum aortic gradient (mmHg)	55.5 ± 18.97	57.1 ± 19.53	0.674
Pre-operative mean aortic gradient (mmHg)	35.9 ± 12.47	36.2 ± 12.66	0.900
Pre-operative aortic valve area (cm^2)	0.78 ± 0.22	0.74 ± 0.15	0.387
Pre-operative PASP (mmHg)	46.1 ± 12.27	48.0 ± 11.40	0.386
Pre-operative TAPSE (cm)	1.66 ± 0.26	1.76 ± 0.21	0.015
Pre-operative aortic root diameter (cm)	2.74 ± 0.65	2.78 ± 0.39	0.149
Severe aortic regurgitation	12 (30.0%)	8 (10.5%)	0.017
Pre-Operative Laboratory Values			
Sheath size (Fr)	17.7 ± 2.20	14.9 ± 1.23	<0.001
Hemoglobin (g/dL)	11.5 ± 1.69	11.42 ± 1.92	0.830
Creatinine (mg/dL)	1.36 ± 0.64	1.34 ± 0.83	0.470
AST (IU/L)	21.8 ± 9.21	28.99 ± 24.86	0.110
Procedural Data & Postoperative Outcomes			
Valve size (mm)	27.3 ± 2.33	30.7 ± 3.23	<0.001
Sheath size (Fr)	17.7 ± 2.20	14.9 ± 1.23	<0.001
Hospitalization duration (days)	5.6 ± 3.38	6.3 ± 4.30	0.612

Table 5 (cont). Comparison of balloon-expandable and self-expanding valves in patients with severely reduced ejection fraction (LVEF < 40%) and severe aortic stenosis

Variables	Balloon-expandable valve (n = 40)	Self-expanding valve (n = 76)	*P*
Long-term follow-up duration (days)	1575.5 (712.75–2740.25)	999.0 (607.75–1406.0)	0.001
Periprocedural MI	1 (2.5%)	2 (2.6%)	1.000
Periprocedural stroke	1 (2.5%)	3 (3.9%)	1.000
Postoperative acute kidney injury	7 (17.5%)	10 (13.2%)	0.725
Major vascular complication	4 (10.0%)	12 (15.8%)	0.564
Minor vascular complication	4 (10.0%)	7 (9.2%)	1.000
Major bleeding	4 (10.0%)	14 (18.4%)	0.357
Coronary obstruction	1 (2.5%)	1 (1.3%)	1.000
Device embolization	0 (0%)	1 (1.3%)	1.000
IABP/ECMO use	3 (7.5%)	1 (1.3%)	0.118
Surgery due to peripheral complication	3 (7.5%)	3 (3.9%)	0.414
New permanent pacemaker implantation	3 (7.5%)	3 (3.9%)	0.414
Postoperative maximum aortic gradient (mmHg)	15.8 ± 7.73	13.4 ± 6.45	0.083
Postoperative mean aortic gradient (mmHg)	8.76 ± 3.98	7.25 ± 3.95	0.033
Postoperative LVEF (%)	35.1 ± 8.04	36.6 ± 8.93	0.457
Postprocedural LVEF change (%)	4.24 ± 6.44	3.58 ± 7.44	0.916
Postoperative PASP (mmHg)	41.9 ± 11.13	40.9 ± 12.59	0.586
Device success	26 (65.0%)	53 (69.7%)	0.756
Technical success	31 (77.5%)	61 (80.3%)	0.914
Severe mitral regurgitation	9 (22.5%)	16 (21.1%)	1.000
Severe tricuspid regurgitation	2 (5.0%)	9 (11.8%)	0.326
Moderate–severe PVL	3 (9.1%)	8 (11.8%)	1.000
In-hospital mortality	8 (20.0%)	4 (5.3%)	0.022
Long-term mortality	19 (47.5%)	30 (39.5%)	0.526

ACEi, Angiotensin-converting enzyme inhibitor; ARB, Angiotensin II receptor blocker; ARNI, Angiotensin receptor–neprilysin inhibitor; AST, Aspartate aminotransferase; COPD, Chronic obstructive pulmonary disease; ECMO, Extracorporeal membrane oxygenation; IABP, Intra-aortic balloon pump; LVEF, Left ventricular ejection fraction; MI, Myocardial infarction; MRA, Mineralocorticoid receptor antagonist; PASP, Pulmonary artery systolic pressure; PVL, Paravalvular leak; SGLT-2i, Sodium–glucose cotransporter-2 inhibitor; TAPSE, Tricuspid annular plane systolic excursion.

Table 6. Multivariate Cox regression analysis for the prediction of long-term mortality in patients with advanced heart failure (LVEF < 40%)

Covariate	HR	95% CI	*P*
Age	1.011	0.981–1.043	0.468
COPD	1.914	1.027–3.568	0.041
CAD	1.278	0.619–2.640	0.507
BEV vs. SEV	0.655	0.348–1.233	0.190
Mean aortic gradient (per 1 mmHg)	0.968	0.943–0.993	0.011

BEV, Balloon-expandable valve; CAD, Coronary artery disease; CI, Confidence interval; COPD, Chronic obstructive pulmonary disease; HR, Hazard ratio, LVEF, Left ventricular ejection fraction; SEV, Self-expanding valve.

Discussion

Reduced LVEF has consistently been linked to poorer outcomes after TAVR, including increased risks of in-hospital and long-term death as well as adverse cardiac events.[4–11] Within this group, patients exhibiting the low-flow, low-gradient phenotype experience the most unfavorable prognosis, with mortality exceeding that of both paradoxical low-gradient and high-gradient subtypes.[8–11] Given the increased hemodynamic vulnerability of patients with LVSD, complications such as paravalvular leak, arrhythmia, cardiac tamponade, hypotension, acute kidney injury, bleeding, and prosthetic valve dysfunction may be less well tolerated. Consequently, determining whether valve design or functional differences influence outcomes carries particular clinical relevance in this vulnerable population.

Previous studies comparing SEVs and BEVs have primarily focused on outcomes such as PVR, high-grade atrioventricular block, recapturability, and postprocedural hemodynamics. The CHOICE trial (Comparison of Balloon-Expandable Versus Self-Expanding Transcatheter Aortic Valve Implantation) demonstrated higher device success with BEVs, driven by lower rates of more-than-mild PVR and new permanent pacemaker implantation in the overall TAVR population.[16] Conversely, the SOLVE-TAVI trial (Comparison of Second-Generation Self-Expandable Versus Balloon-Expandable Valves and General Versus Local Anesthesia in Transcatheter

Aortic Valve Implantation)—comparing newer-generation systems—found no meaningful differences between valve types regarding mortality, PVR, or pacemaker implantation.[17] The extended follow-up of CHOICE similarly demonstrated that five-year all-cause mortality and clinically significant PVR rates were comparable, although SEVs maintained lower residual gradients.[20] Similarly, the SMART trial (Comparison of Self-Expanding Versus Balloon-Expandable Valves in Patients With Small Aortic Annuli Undergoing Transcatheter Aortic Valve Replacement), which focused on TAVR in patients with small aortic annuli, showed that SEVs provided lower transvalvular gradients and less bioprosthetic valve dysfunction, with comparable new pacemaker rates.[21] Despite these findings, most pivotal trials have not specifically analyzed outcomes in patients with reduced LVEF, and data in this subgroup remain limited. Considering the distinct hemodynamic and procedural profiles of BEVs and SEVs, evaluating their comparative performance in patients with LVSD is crucial for optimizing valve selection and improving long-term outcomes.

Mustafa et al.[24] compared SEVs and BEVs among patients with LVEF ≤ 40% and found similar early outcomes, pacemaker rates, long-term survival, and quality-of-life measures at one year. In that study, BEVs were associated with higher transvalvular gradients, whereas SEVs showed higher rates of PVR. Evidence from studies with longer follow-up durations has been limited until recently. Nakase et al.[25] analyzed five-year follow-up in a similar population (TAVR patients with LVEF < 50%) and observed higher all-cause mortality in the SEV group, whereas device success, PVR severity, pacemaker implantation, and cardiovascular mortality at one and five years were comparable. Notably, the BEV group demonstrated higher mean transvalvular gradients. However, as this study also had a retrospective design, residual confounding and selection bias may have influenced the observed differences in long-term mortality. In the present study, with a median follow-up approaching three years, the SEV group demonstrated significantly lower postoperative transvalvular gradients and numerically lower long-term mortality. Nonetheless, these differences likely reflect baseline disparities—specifically, the older age and higher EuroSCORE II values observed in the BEV group—rather than an intrinsic difference in valve performance. In the Cox regression analyses, valve type did not emerge as an independent determinant of long-term mortality, and Kaplan–Meier analysis similarly demonstrated no survival difference between BEV and SEV recipients.

Determinants of long-term mortality among patients with reduced ejection fraction undergoing TAVR are not fully defined. Ludwig et al.[5] identified male sex, COPD, stroke volume index, pulmonary hypertension, atrial fibrillation, and non-transfemoral access as independent one-year predictors, though laboratory, procedural, and imaging parameters were not incorporated. However, that analysis did not include comprehensive clinical or procedural variables such as laboratory data, detailed echocardiographic parameters, or angiographic findings. In the TOPAS-TAVI registry (True or Pseudo Severe Aortic Stenosis–Transcatheter Aortic Valve Implantation registry),[12] COPD and lower hemoglobin levels independently predicted long-term mortality after a median follow-up of 21 months in patients with low-flow, low-gradient aortic stenosis. The present study expands upon these findings with a more comprehensive dataset and a longer observation period. Consistent with prior findings, COPD and lower hemoglobin levels independently predicted long-term mortality. Additionally, advanced age, the presence of coronary artery disease, and reduced serum albumin were significant contributors. Notably, lower preoperative mean aortic gradients were also linked to higher mortality, aligning with existing evidence that LFLG severe aortic stenosis confers an adverse prognosis. These results highlight that even among patients with reduced ejection fraction, lower preprocedural gradients continue to serve as a marker of adverse clinical outcomes after TAVR.

In patients with severe LV dysfunction (LVEF < 40%) undergoing TAVR, our findings demonstrate that balloon-expandable and self-expanding valves yield broadly comparable clinical outcomes, despite notable baseline and procedural differences. The balloon-expandable group presented with slightly more advanced right ventricular dysfunction—as reflected by lower TAPSE—and a higher prevalence of concomitant severe aortic regurgitation, suggesting a potentially more complex hemodynamic substrate. Additionally, larger sheath requirements and smaller prosthesis diameters reflect known design distinctions between platforms. Despite these differences, early periprocedural events—including stroke, MI, acute kidney injury, and vascular complications—were similar across both groups, reinforcing the procedural safety of modern TAVR devices even in high-risk, low-ejection fraction (EF) populations. An important consideration when interpreting the higher in-hospital mortality observed in the balloon-expandable cohort is the temporal distribution of cases. Because the earliest procedures in our program were primarily performed with balloon-expandable valves, it is plausible that the learning curve may have contributed to the increased early mortality signal in this group. As operator and institutional experience grew, procedural refinement and complication management likely improved, which may explain the subsequently lower in-hospital mortality rates observed in later cases. This pattern suggests that at least part of the early mortality difference may be attributable to procedural maturation rather than intrinsic device-related risk. Taken together, long-term mortality, device success, and technical performance were comparable between groups, indicating that both valve types can be effectively used in patients with severely impaired systolic function. These results support individualized valve selection based not only on anatomical suitability but also on operator preference and center experience, as both platforms demonstrated acceptable safety and durability in this challenging patient subset. Matta et al.[26] reported improved long-term survival in patients with advanced heart failure and severe aortic stenosis who underwent SEV implantation compared with those receiving BEV, attributing this difference to lower postoperative transvalvular gradients. However, their study included a relatively small sample size and a retrospective design, making it susceptible to confounding and unmeasured bias. While our analysis demonstrated comparable long-term mortality outcomes between valve types, further prospective and randomized clinical trials are needed before definitive conclusions can be drawn.

Limitations

Several limitations should be considered. First, this study was a single-center, retrospective investigation, which may restrict the generalizability of its findings. Second, computed tomography–based anatomical data were not available, precluding detailed evaluation of annular geometry, valve sizing, and calcification burden. Third, the proportion of newer-generation devices was relatively low, and outcomes with contemporary valve systems may differ. Fourth, because detailed documentation of the specific causes of death was not consistently available, we were unable to differentiate cardiovascular from non-cardiovascular mortality, which may limit the mechanistic interpretation of our findings. Finally, although EuroSCORE II and age differed statistically between groups in the overall patient cohort, the numerical differences were modest and unlikely to have introduced a clinically meaningful imbalance; nevertheless, residual confounding related to baseline risk cannot be entirely excluded, and unmeasured confounders inherent to the retrospective design may also be present. Therefore, prospective multicenter studies with higher representation of current-generation valve platforms are warranted to confirm these observations in patients with reduced systolic function.

Conclusion

In patients with impaired left ventricular systolic function undergoing TAVR, BEV and SEV systems demonstrated comparable procedural success and long-term outcomes. Although self-expanding valves provided lower postoperative gradients, valve type did not independently predict mortality. Instead, older age, COPD, coronary artery disease, lower preoperative mean aortic gradient, and reduced hemoglobin and albumin levels predicted long-term mortality. Valve selection may therefore rely more on anatomical suitability and operator preference than on differences in survival.

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Informed Consent: Written informed consent was obtained from the participants.

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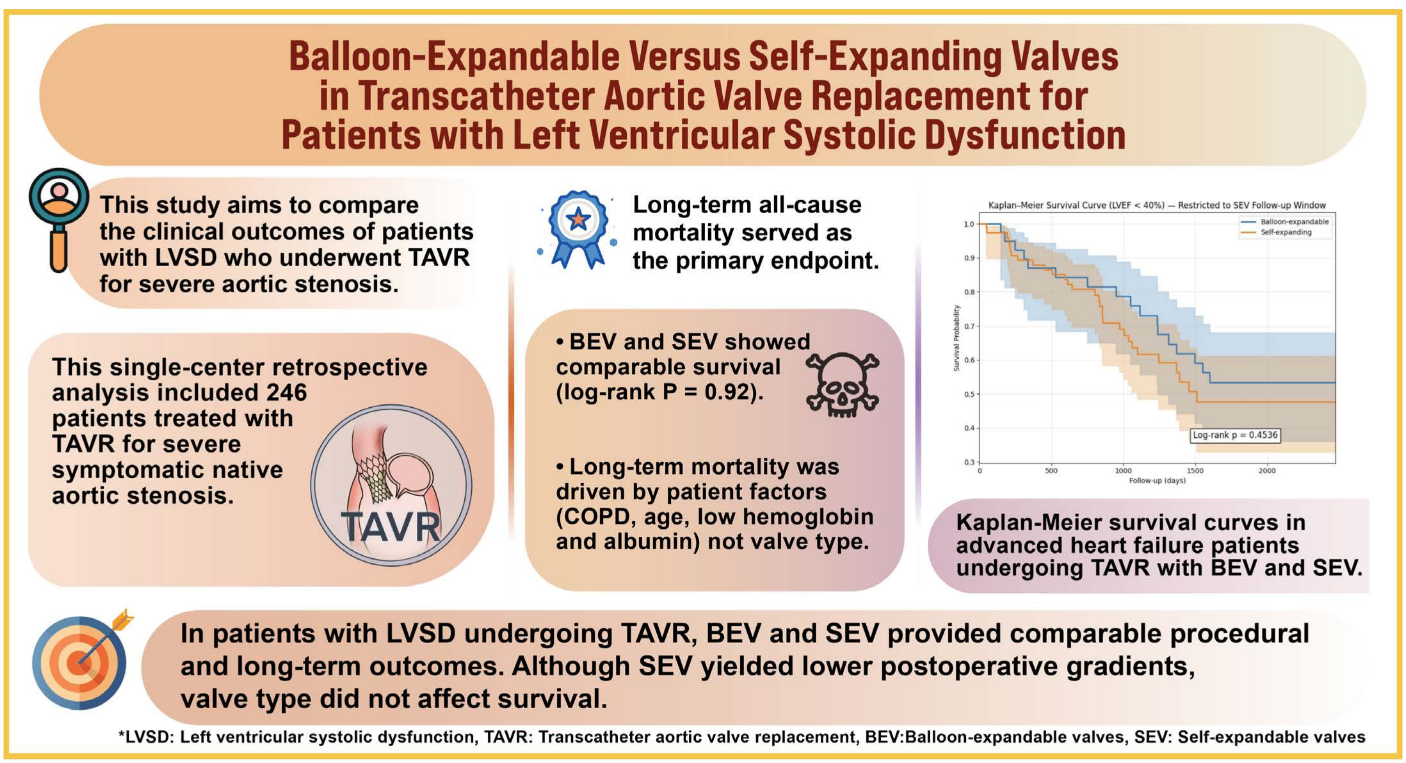

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