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[Aditya M. Desai](#)<sup>\*</sup>, [Simran Gill](#), Aparna Manoj, Naishal Mandal, Haidar Hajeh, Darshi Desai, [Haresh Gandhi](#), Prabhdeep S. Sethi, [James Blankenship](#), [Tanawan Riangwiwat](#)

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Article

# Comparing Direct TAVR to Balloon Aortic Valvuloplasty-TAVR in Patient with Cardiogenic Shock and Severe Aortic Stenosis—A TriNetX—Based Study

**Running Title: Direct TAVR vs BAV-TAVR in Cardiogenic Shock and Aortic Stenosis**

Aditya M. Desai <sup>1\*</sup>, Simran Gill <sup>1</sup>, Aparna Manoj <sup>1</sup>, Naishal Mandal <sup>2</sup>, Haidar Hajeh <sup>1</sup>, Darshi Desai <sup>1</sup>, Haresh Gandhi <sup>1</sup>, Prabhdeep S. Sethi <sup>1</sup>, James Blankenship <sup>3</sup> and Tanawan Riangwiwat <sup>1</sup>

<sup>1</sup> Department of Internal Medicine, University of California, Riverside School of Medicine, Riverside, CA, USA

<sup>2</sup> Department of Internal Medicine, Hurley Medical Center, Michigan State University of Human Medicine, Flint, MI, USA

<sup>3</sup> Division of Cardiology, University of New Mexico, Albuquerque, NM, USA

\* Correspondence: aditya.desai@medsch.ucr.edu

## Abstract

**Aim:** Severe aortic stenosis (AS) with cardiogenic shock (CS) presents a complex clinical challenge. For these patients, the optimal management strategy- either direct transcatheter aortic valve replacement (TAVR) or a staged approach with balloon aortic valvuloplasty (BAV) as a bridge to TAVR (BAV-TAVR) is uncertain. We aimed to compare the outcomes of these two strategies. **Methods:** We conducted a retrospective cohort study using TriNetX database. In this study, we identified patients with CS undergoing TAVR or BAV-TAVR. After matching propensity scores, 198 patients were analyzed in each group (total 396). The primary outcome was major adverse cardiovascular events (MACE) at 30 days, 1 year, and 3 years. **Results:** The analysis included 396 matched patients (198 in each cohort). There was no significant difference in the primary endpoint of MACE at 30 days between the staged BAV and direct TAVR groups (HR 1.14; 95% CI 0.79–1.64; p=0.91), and this finding was consistent at 1 and 3 years with HR 1.20 and 1.17 respectively. Similarly, no differences were observed in secondary outcomes including all-cause mortality, stroke, and new permanent pacemaker implantation, at 30 days, 1, and 3 years. **Conclusion:** For patients with severe AS complicated by CS, a staged strategy of using BAV-TAVR resulted in comparable short and long-term outcomes to direct TAVR. These findings suggest that BAV is a viable and safe bridging option in high-risk patients whose immediate candidacy for definitive therapy is uncertain.

**Keywords:** aortic stenosis; cardiogenic shock; TAVR; heart failure

## 1. Introduction

Aortic stenosis (AS) is the most common valvular disease in the developed world and carries high morbidity and mortality once symptomatic.[1–4] Without valve replacement, life expectancy is only 2–3 years.[4] Cardiogenic shock (CS), a severe complication of AS, is marked by low cardiac output and end-organ hypoperfusion, and remains associated with extremely high mortality. [5,6]

Balloon aortic valvuloplasty (BAV) was historically used as palliative therapy due to its temporary hemodynamic benefit and poor long-term durability.[7] With the advent of TAVR, interest has grown in BAV as a stabilizing or bridging therapy. Current guidelines support BAV as a Class IIb option in critically ill patients, such as those with refractory pulmonary edema or CS, when immediate valve replacement is not feasible.[8] Contemporary studies suggest BAV can be

performed safely in these high-risk settings with careful attention to timing, as intervention within 48 hours of shock onset is critical for the best outcomes.[9–12]

As life expectancy increases, the burden of AS will inevitably rise. Given the poor prognosis for these patients and a lack of robust evidence-based guidelines, more research is required. This study aims to assess BAV's role in bridging to TAVR (BAV-TAVR) compared to direct TAVR in patients with severe AS complicated by cardiogenic shock.

## 2. Method

This retrospective cohort study utilized data from the TriNetX U.S. Collaborative Network, a federated cloud-based research platform comprising de-identified electronic health records from over 72 healthcare organizations across the United States. We identified adult patients diagnosed with severe aortic valve stenosis using ICD-10 codes I35.0 (nonrheumatic aortic valve stenosis), with concurrent cardiogenic shock (ICD-10 code R57.0), to form the eligible population for inclusion.

### Cohort Definition:

Two mutually exclusive treatment cohorts were defined based on procedural codes.

Cohort 1 included patients who underwent TAVR alone, identified using CPT codes 33361 to 33369. Patients with prior surgical aortic valve replacement were excluded using CPT codes 33405, 33406 and 33410-33413, resulting in 1,701 eligible individuals.

Cohort 2 consisted of patients who underwent TAVR as a separate procedure within 30 days of BAV. These individuals were identified using a combination of CPT codes 33361–33369 (TAVR) and CPT 92986 (BAV) and were similarly excluded if prior surgical valve replacement was recorded (CPT 33405, 33406 or 33410-33413), yielding 201 eligible patients.

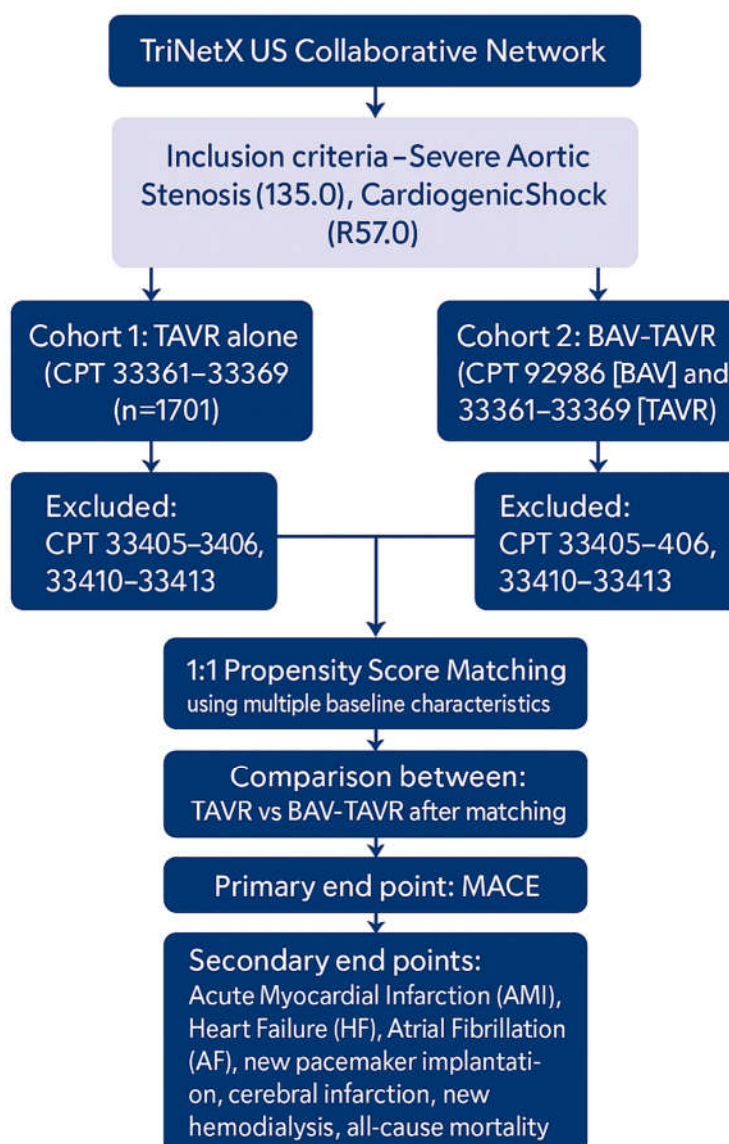
To minimize confounding, we performed 1:1 propensity score matching between the two cohorts using a nearest-neighbor algorithm without replacement. Matching was based on multiple baseline characteristics including age, sex, race, comorbidities (e.g., ischemic heart disease, heart failure, atrial fibrillation, diabetes, hypertension, chronic kidney disease, cerebrovascular accident, cardiac arrest, malnutrition, obesity/ overweight), procedures (e.g., cardiac assist including Impella and IABP, ECMO/ECLS services, emergent endotracheal intubation), lab values (e.g., hemoglobin, creatinine, albumin, HbA1c, BMI, BNP, LVEF, troponin) and Medication (e.g., vasopressors). After matching, the final analytic sample comprised 396 patients: 198 patients who underwent direct TAVR alone and 198 who received BAV-TAVR.

Outcomes were assessed over three predefined timeframes: 30 days, 1 year, and 3 years following the index procedure.

The primary endpoint was the incidence of major adverse cardiovascular events (MACE), defined as a composite of all-cause mortality, acute myocardial infarction (AMI), and stroke. Secondary endpoints included individual incidence of acute myocardial infarction, heart failure, new pacemaker implantation, atrial fibrillation, cerebral infarction (stroke), new hemodialysis, and all-cause mortality. Figure 1 depicts the schematics of study design.

A separate analysis of treatment pathway was performed to determine the median time to TAVR which included patients from 40 HCOs and was not a part of the study. However, this was done to know the median time to TAVR in patients who underwent BAV.

All statistical analyses were performed within the TriNetX platform on October 2<sup>nd</sup> 2025, which ensures real-time access to de-identified, aggregated patient-level data while maintaining compliance with HIPAA and institutional ethical standards. Institutional Board Review was not required due to deidentified nature of the database. Cox-proportional hazard analysis was done with the TriNetX inbuilt software to obtain the results which were reported as hazard ratio, p-value of < 0.05 was considered significant. Artificial intelligence was used to generate tables and figures from raw data extracted from the database.



**Figure 1.** Schematic of study design using TriNetX US Collaborative Network. **Legend:** BAV = Balloon Aortic Valvuloplasty; TAVR = Transcatheter Aortic Valve Replacement; MACE = Major Adverse Cardiovascular Events.

### 3. Results

#### 3.1. Baseline Characteristics

Prior to propensity score matching, significant differences were observed between patients undergoing direct TAVR ( $n = 1,701$ ) and those receiving BAV-TAVR ( $n = 201$ ). Patients in the BAV-TAVR group presented with a higher burden of comorbidities. Notably, the prevalence of heart failure was significantly greater in the BAV-TAVR cohort (97.5% vs. 80.7%;  $p < 0.001$ ). Other cardiovascular diagnoses, including ischemic heart disease (87.1% vs. 77.8%;  $p = 0.002$ ) and atrial fibrillation or flutter (61.2% vs. 50.4%;  $p = 0.004$ ), were also significantly more common. Malnutrition was more frequently documented among BAV-TAVR patients (26.9% vs. 15%;  $p < 0.001$ ), and they had significantly higher use of cardiac assist procedures (31.8% vs. 8.6%;  $p < 0.001$ ), emergency endotracheal intubation (14.4% vs. 5.4%;  $p < 0.001$ ), and extracorporeal membrane oxygenation (5% vs. 1.5%;  $p = 0.001$ ).

Laboratory profiles further highlighted the severity of illness in the BAV-TAVR cohort. Hemoglobin ( $9.7 \pm 2.4$  vs.  $11.1 \pm 2.3$  g/dL;  $p < 0.001$ ), serum albumin ( $3.1 \pm 0.5$  vs.  $3.4 \pm 0.6$  g/dL;  $p < 0.001$ ), and natriuretic peptide B levels ( $8,134 \pm 12,970$  vs.  $3,788 \pm 8,156$  pg/mL;  $p < 0.001$ ) were significantly different between groups, suggesting greater hemodynamic compromise and malnutrition in the BAV-TAVR cohort. The median time to TAVR was 4 days.

Following 1:1 propensity score matching, 198 patients were included in each cohort. After matching, there were no statistically significant differences in baseline demographics, comorbidities, procedural characteristics, or laboratory values (all  $p > 0.05$ ), indicating successful balancing of the cohorts for comparative analysis. Table 1 shows the patient characteristics before and after propensity matching respectively.

**Table 1.** Baseline Patient Characteristics Before and After Propensity Score Matching.

Characteristic	Before Propensity Score Matching			After Propensity Score Matching		
	Direct TAVR (n=1,701)	BAV-TAVR (n=201)	p-value	Direct TAVR (n=198)	BAV-TAVR (n=198)	p-value
<b>Demographics</b>						
Age at Index, mean $\pm$ SD	75.5 $\pm$ 10.6	76.4 $\pm$ 9.3	0.23	76.4 $\pm$ 9.8	76.3 $\pm$ 9.2	0.96
Male, n (%)	1,003 (59.0)	112 (55.7)	0.37	114 (57.6)	112 (56.6)	0.83
White, n (%)	1,347 (79.2)	145 (72.1)	0.02	144 (72.7)	144 (72.7)	1.00
Black or African American, n (%)	99 (5.8)	10 (5.0)	0.62	11 (5.6)	10 (5.1)	0.82
Asian, n (%)	46 (2.7)	11 (5.5)	0.02	10 (5.1)	11 (5.6)	0.82
<b>Diagnoses</b>						
Heart failure, n (%)	1,372 (80.7)	196 (97.5)	<0.001	193 (97.5)	193 (97.5)	1.00
Ischemic heart diseases, n (%)	1,323 (77.8)	175 (87.1)	0.002	172 (86.9)	172 (86.9)	1.00
Hypertensive diseases, n (%)	1,344 (79.0)	171 (85.1)	0.04	167 (84.3)	169 (85.4)	0.77
Atrial fibrillation and flutter, n (%)	858 (50.4)	123 (61.2)	0.004	120 (60.6)	121 (61.1)	0.91
Chronic kidney disease, n (%)	803 (47.2)	108 (53.7)	0.08	106 (53.5)	107 (54.0)	0.92
Diabetes mellitus, n (%)	698 (41.0)	94 (46.8)	0.11	97 (49.0)	92 (46.5)	0.61

Malnutrition, n (%)	255 (15.0)	54 (26.9)	<0.001	53 (26.8)	53 (26.8)	1.00
Cerebrovascular diseases, n (%)	376 (22.1)	43 (21.4)	0.81	51 (25.8)	43 (21.7)	0.34
Overweight and obesity, n (%)	393 (23.1)	44 (21.9)	0.69	47 (23.7)	44 (22.2)	0.72
Cardiac arrest, n (%)	157 (9.2)	26 (12.9)	0.09	37 (18.7)	26 (13.1)	0.13
<b>Procedures</b>						
Impella and IABP, n (%)	147 (8.6)	64 (31.8)	<0.001	63 (31.8)	62 (31.3)	0.91
Emergency Endotracheal Intubation, n (%)	92 (5.4)	29 (14.4)	<0.001	26 (13.1)	28 (14.1)	0.77
ECMO or ECLS, n (%)	26 (1.5)	10 (5.0)	0.001	10 (5.1)	10 (5.1)	1.00
<b>Medications</b>						
Vasopressors, n (%)	756 (44.4)	163 (81.1)	<0.001	161 (81.3)	160 (80.8)	0.89
<b>Labs</b>						
Hemoglobin (g/dL), mean $\pm$ SD	11.1 $\pm$ 2.3	9.7 $\pm$ 2.4	<0.001	10.0 $\pm$ 2.5	9.8 $\pm$ 2.4	0.33
Creatinine (mg/dL), mean $\pm$ SD	1.6 $\pm$ 1.4	1.6 $\pm$ 1.5	0.91	1.7 $\pm$ 1.4	1.6 $\pm$ 1.5	0.95
Albumin (g/dL), mean $\pm$ SD	3.4 $\pm$ 0.6	3.1 $\pm$ 0.5	<0.001	3.1 $\pm$ 0.5	3.1 $\pm$ 0.5	0.68
BMI, mean $\pm$ SD	28.5 $\pm$ 6.7	28.1 $\pm$ 6.3	0.48	28.3 $\pm$ 6.5	28.2 $\pm$ 6.3	0.88
Natriuretic peptide B (pg/mL), mean $\pm$ SD	3,788 $\pm$ 8,156	8,134 $\pm$ 12,970	<0.001	7,839 $\pm$ 11,747	7,856 $\pm$ 13,029	0.99
LVEF (%), mean $\pm$ SD	37.2 $\pm$ 17.6	35.0 $\pm$ 17.5	0.35	32.7 $\pm$ 14.8	35.2 $\pm$ 17.7	0.39
Troponin Icardiac (ng/mL), mean $\pm$ SD	4.1 $\pm$ 25.1	5.2 $\pm$ 8.1	0.77	5.4 $\pm$ 9.7	5.2 $\pm$ 8.1	0.91

Data presented as n (%) or mean  $\pm$  standard deviation (SD). TAVR: Transcatheter Aortic Valve Replacement; BAV: Balloon Aortic Valvuloplasty; IABP: Intra-aortic balloon pump; ECMO: Extracorporeal Membrane Oxygenation; ECLS: Extracorporeal Life Support; BMI: Body Mass Index; LVEF: Left Ventricular Ejection Fraction.

### 3.2. 30 Days Clinical Outcomes

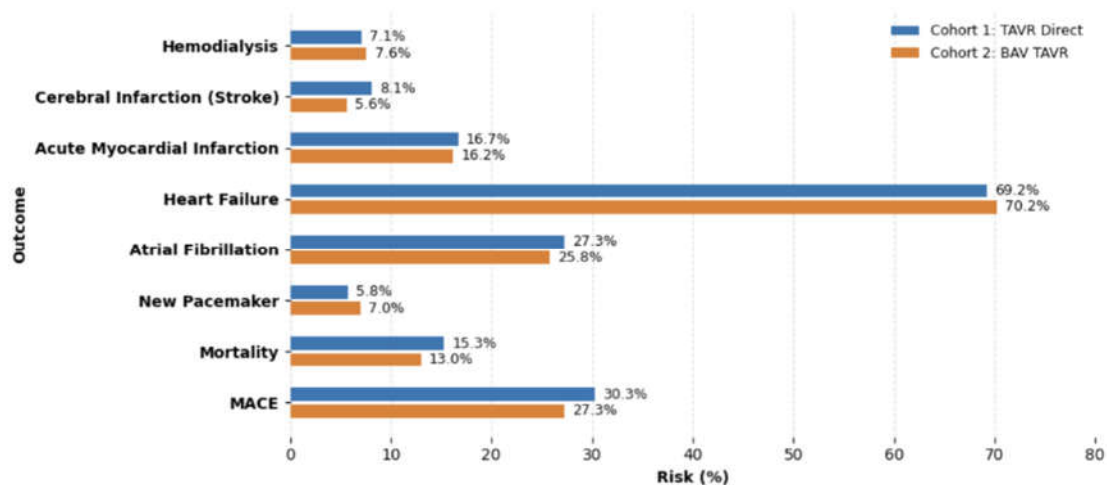
At 30 days, there were no statistically significant differences between the direct TAVR and BAV-TAVR groups across all measured clinical outcomes. MACE occurred in 30.3% of patients in the direct TAVR group compared with 27.3% in the BAV-TAVR group (hazard ratio [HR]: 1.14; 95% confidence interval [CI]: 0.79–1.64;  $p = 0.91$ ). All-cause mortality was observed in 15.3% of patients in the direct TAVR group and 13% of patients in the BAV-TAVR group (HR: 1.19; 95% CI: 0.70–2.04  $p = 0.71$ ).

Other secondary outcomes were similarly balanced between groups. New permanent pacemaker implantation occurred in 5.8% of direct TAVR patients versus 7% in the BAV-TAVR group ( $p = 0.47$ ). The incidence of atrial fibrillation was 27.3% in the direct TAVR group and 25.8% in the BAV-TAVR group ( $p = 0.10$ ). Heart failure occurred in 69.2% of the direct TAVR group compared with 70.2% of the BAV-TAVR group ( $p = 0.33$ ). There were no significant differences in the rates of AMI (16.7% vs. 16.2%;  $p = 0.99$ ), cerebral infarction (8.1% vs. 5.6%;  $p = 0.93$ ), or new requirement for hemodialysis (7.1% vs. 7.6%;  $p = 0.35$ ). Detailed results are shown in Table 2 and Figure 2.

**Table 2.** Clinical Outcomes at 30 Days (After Matching).

Outcome	TAVR Direct (n, %)	BAV TAVR (n, %)	Hazard Ratio (95% CI)	HR p-value
MACE	60 (30.3%)	54 (27.3%)	1.14 (0.79, 1.64)	0.91
Mortality	29 (15.3%)	25 (13.0%)	1.19 (0.70, 2.04)	0.71
New Pacemaker	11 (5.8%)	13 (7.0%)	0.83 (0.37, 1.86)	0.47
Atrial Fibrillation	54 (27.3%)	51 (25.8%)	1.09 (0.75, 1.60)	0.10
Heart Failure	137 (69.2%)	139 (70.2%)	1.01 (0.80, 1.28)	0.33
Acute Myocardial Infarction	33 (16.7%)	32 (16.2%)	1.03 (0.63, 1.68)	0.99
Cerebral Infarction (Stroke)	16 (8.1%)	11 (5.6%)	1.47 (0.68, 3.18)	0.93
Hemodialysis	14 (7.1%)	15 (7.6%)	0.93 (0.45, 1.92)	0.35

MACE: Major Adverse Cardiovascular Events; CI: Confidence Interval.



**Figure 2.** Risk Percentages of Clinical Outcomes at 30 Days After Matching.

### 3.3. 1-Years Clinical Outcomes

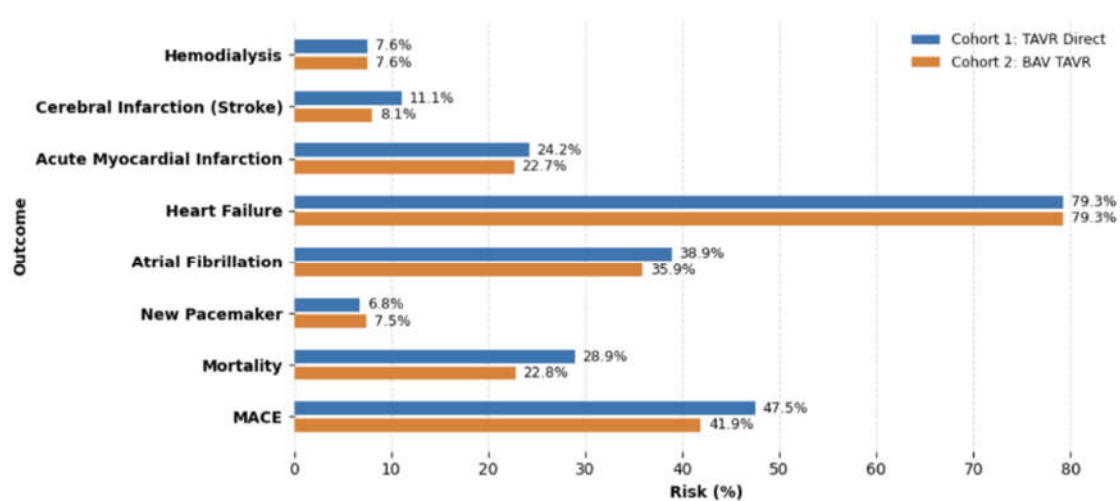
At one-year follow-up, outcomes remained comparable between the two groups. MACE was observed in 47.5% of patients undergoing direct TAVR and 41.9% of those in the BAV-TAVR group (HR: 1.20; 95% CI: 0.89–1.61  $p = 0.84$ ). Mortality was 28.9% in the direct TAVR group compared to 22.8% in the BAV-TAVR group (HR: 1.32; 95% CI: 0.90–1.96;  $p = 0.64$ ).

New pacemaker implantation are similar in both groups (6.8% vs. 7.5%;  $p = 0.95$ ), as did atrial fibrillation (38.9% vs. 35.9%;  $p = 0.88$ ). Incidence of heart failure (79.3% in both;  $p = 0.69$ ), AMI (24.2% vs. 22.7%;  $p = 0.62$ ), cerebral infarction (11.1% vs. 8.1%;  $p = 0.80$ ), and new hemodialysis (7.6% in both;  $p = 0.21$ ) were also statistically indistinguishable. Detailed results are shown in Table 3 and Figure 3.

**Table 3.** Clinical Outcomes at 1 Year (After Matching).

Outcome	TAVR (n, %)	Direct BAV TAVR (n, %)	Hazard Ratio (95% CI)	HR value	p-value
MACE	94 (47.5%)	83 (41.9%)	1.20 (0.89, 1.61)	0.84	
Mortality	55 (28.9%)	44 (22.8%)	1.32 (0.90, 1.96)	0.64	
New Pacemaker	13 (6.8%)	14 (7.5%)	0.91 (0.43, 1.95)	0.95	
Atrial Fibrillation	77 (38.9%)	71 (35.9%)	1.13 (0.82, 1.56)	0.88	
Heart Failure	157 (79.3%)	157 (79.3%)	1.05 (0.84, 1.31)	0.70	
Acute Myocardial Infarction	48 (24.2%)	45 (22.7%)	1.10 (0.73, 1.65)	0.62	
Cerebral (Stroke) Infarction	22 (11.1%)	16 (8.1%)	1.44 (0.75, 2.73)	0.80	
Hemodialysis	15 (7.6%)	15 (7.6%)	1.00 (0.49, 2.04)	0.21	

MACE: Major Adverse Cardiovascular Events; CI: Confidence Interval.



**Figure 3.** Risk Percentages of Clinical Outcomes at 1 Year After Matching.

### 3.4. 3-Years Clinical Outcomes

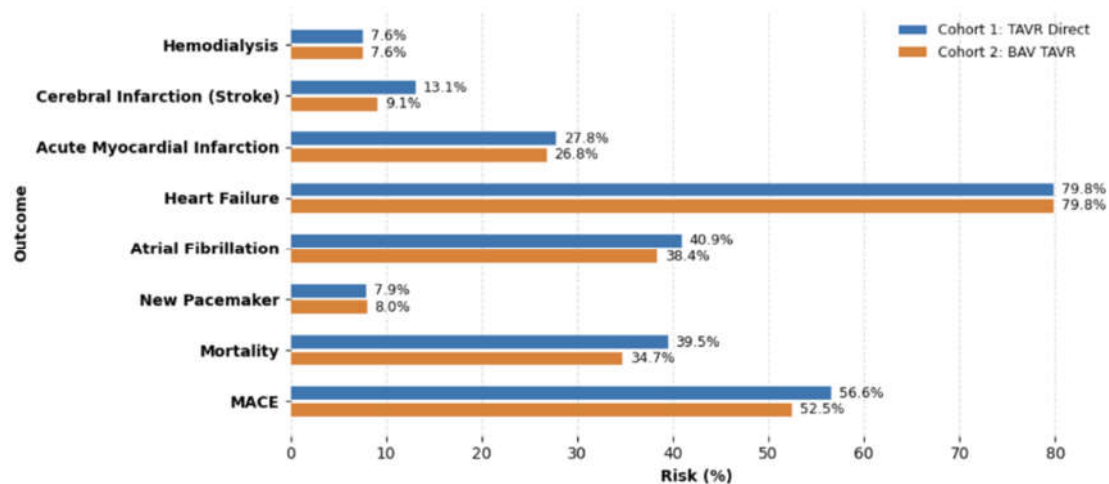
By three years post-procedure, long-term outcomes remained consistent with earlier findings. The cumulative incidence of MACE was 56.6% in the direct TAVR group and 52.5% in the BAV-TAVR group (HR: 1.17; 95% CI: 0.89–1.53;  $p = 0.67$ ). Mortality was 39.5% for direct TAVR and 34.7% for BAV-TAVR (HR 1.21; 95% CI 0.87–1.69;  $p = 0.46$ ), again showing no statistically significant difference.

Permanent pacemaker implantation occurred in 7.9% of direct TAVR patients and 8.0% of BAV-TAVR patients ( $p = 0.75$ ). Atrial fibrillation was reported in 40.9% and 38.4% of patients, respectively ( $p = 0.81$ ). Heart failure was highly prevalent at three years, occurring in 79.8% of both direct TAVR patients and BAV-TAVR patients ( $p = 0.67$ ). Rates of AMI (27.8% vs. 26.8%;  $p = 0.86$ ), cerebral infarction (13.1% vs. 9.1%;  $p = 0.69$ ), and hemodialysis (7.6% in both;  $p = 0.21$ ) also remained statistically similar. Detailed results are shown in Table 4 and Figure 4. In addition, Figures 5 and 6 depict the Kaplan-Meier survival curves for MACE and mortality at three years respectively.

**Table 4.** Clinical Outcomes at 3 Years (After Matching).

Outcome	TAVR Direct (n, %)	BAV TAVR (n, %)	Hazard Ratio (95% CI)	HR p-value
MACE	112 (56.6%)	104 (52.5%)	1.17 (0.89, 1.53)	0.67
Mortality	75 (39.5%)	67 (34.7%)	1.21 (0.87, 1.69)	0.46
New Pacemaker	15 (7.9%)	15 (8.0%)	0.99 (0.49, 2.03)	0.75
Atrial Fibrillation	81 (40.9%)	76 (38.4%)	1.11 (0.81, 1.52)	0.81
Heart Failure	158 (79.8%)	158 (79.8%)	1.05 (0.84, 1.31)	0.67
Acute Myocardial Infarction	55 (27.8%)	53 (26.8%)	1.09 (0.75, 1.60)	0.86
Cerebral (Stroke) Infarction	26 (13.1%)	18 (9.1%)	1.53 (0.84, 2.79)	0.69
Hemodialysis	15 (7.6%)	15 (7.6%)	1.00 (0.49, 2.04)	0.21

MACE: Major Adverse Cardiovascular Events; CI: Confidence Interval.



**Figure 4.** Risk Percentages of Clinical Outcomes at 3 Years After Matching.

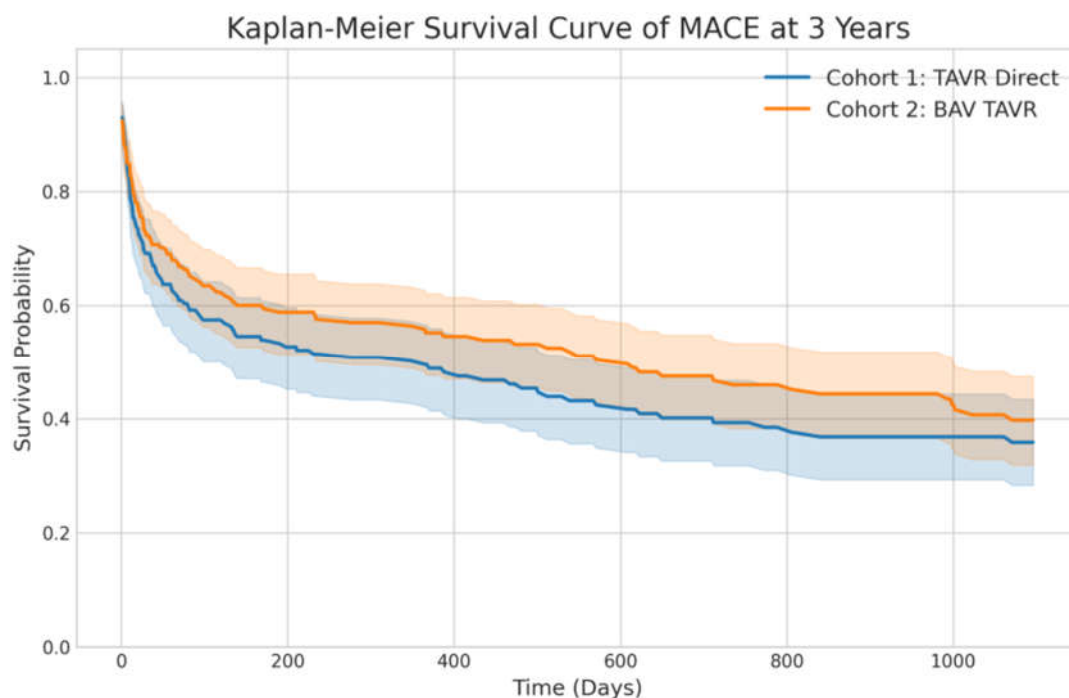


Figure 5. Kaplan-Meier Survival Curve of MACE at 3 Years.

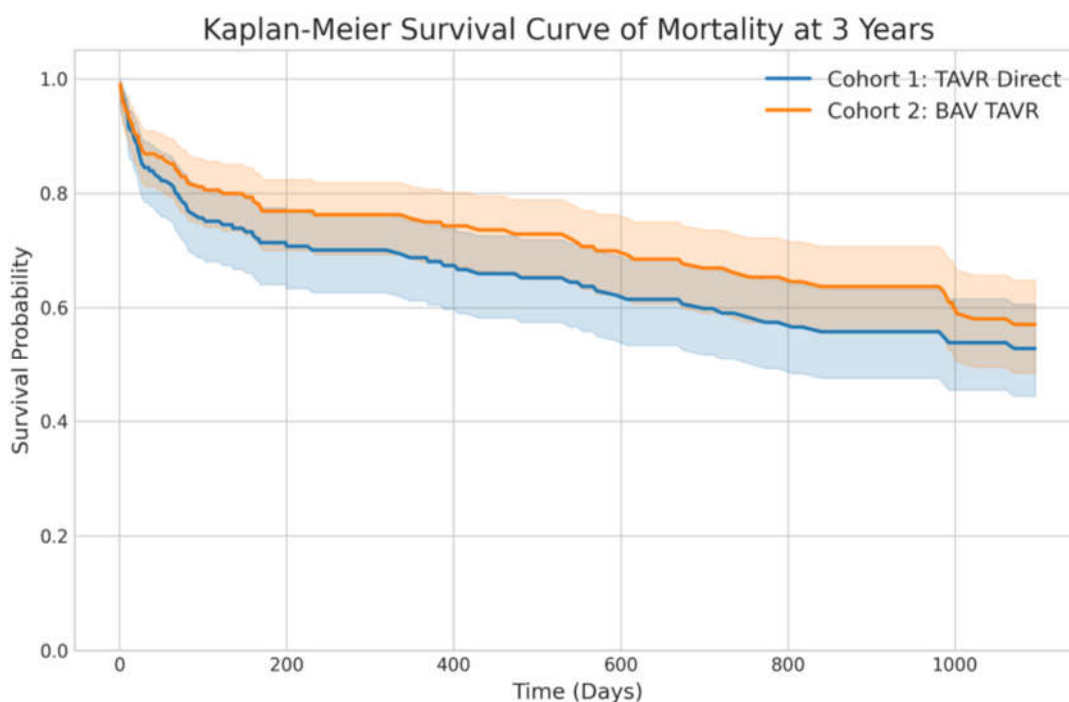


Figure 6. Kaplan-Meier Survival Curve of Mortality at 3 Years.

## 4. Discussion

### 4.1. TAVR vs. BAV-TAVR Outcomes

Our study concluded that in patients with severe AS complicated by CS, BAV-TAVR, in comparison to direct TAVR, does not compromise short or long-term outcomes. These findings align with a large 2020 U.S. registry in which ~40% of patients underwent TAVR after bridging with BAV, typically within 90 days, and demonstrated comparable in-hospital and one-year outcomes to

direct TAVR after propensity matching.[13] That study also reported lower index hospitalization costs in the BAV group. Therefore, BAV remains an important tool for the heart team in triaging, stabilizing, and optimizing patients when immediate TAVR is not yet feasible.

Mechanistically, BAV temporarily relieves stenosis by enlarging the aortic valve area (AVA), lowering transvalvular gradients, and improving stroke volume and organ perfusion.[12] Improvement in renal function after BAV, an important prognostic marker in shock, has been documented following BAV and may explain why dialysis rates were not higher in our bridged group.[14] Hemodynamic improvement has been studied and confirmed these effects. Bularga et al. reported an average 8 mmHg reduction in mean gradient on echo at one week,[15] while Kumar et al. demonstrated a 54% gradient reduction (40 → 18 mmHg) and AVA increase from 0.67 to 1.04 cm<sup>2</sup> when measured invasively immediately post-procedure.[16] Despite differences in measurement timing, both confirmed improved hemodynamics with acceptable procedural safety.

#### 4.2. Role as a Bridge

BAV has mainly served as a temporizing measure in patients too unstable for valve replacement. Early series demonstrated that patients selected for BAV typically had worse baseline status, yet still showed symptomatic and hemodynamic improvements comparable to direct TAVR once stabilized.[10,11,17] Later registry data reinforced that BAV is most beneficial as a bridge, since BAV alone carries high mortality.[11] A contrasting 2024 Japanese registry suggested BAV-TAVR was associated with worse in-hospital outcomes compared to direct TAVR, though this likely reflects unadjusted baseline differences, as those that received BAV were older with more comorbidities.[18]

#### 4.3. Bridge-to-Decision and Diagnostic Value

Beyond serving as a bridge for stabilization and optimization, BAV can assist with determining patient eligibility. Saia et al. demonstrated that BAV can clarify candidacy when the heart team is uncertain, using BAV as a “bridge-to-decision,” as it helped to predict LV contractile reserve and mitral regurgitation grade reduction.[19] In low-LVEF patients, recovery was more likely when baseline gradients were higher (42 vs. 31 mmHg), and nearly all with EF improvement were subsequently selected for definitive valve replacement. Of note, the change in gradients, not AVA, were predictive of recovery.

#### 4.4. Durability and Timing

Recent work has shown that BAV’s hemodynamic effects peak within 6 months, with improvements in EF (>40% at 1 month) predicting suitability for definitive replacement.[20–22] However, durability is limited, with a 2025 meta-analysis finding that delaying TAVR for staged BAV, on average 2 months to almost 1 year, was linked with higher mortality compared to immediate TAVR, although complication rates were similar.[23] These findings emphasize that BAV should be used selectively as a short-term bridge, ideally leading to definitive therapy as soon as possible. The median time in patients getting TAVR post BAV in CS was 4 days in the database.

#### 4.5. Emerging Stepwise Strategies

There are emerging adjunctive strategies. A 2025 case report described a “BAV-PELLA-TAVR” approach, where BAV was combined with Impella support as a stepwise bridge in three elderly patients with severe AS and shock, all of whom survived to definitive TAVR.[24] Similarly, Frerker et al. demonstrated how baseline cardiac output <3L/min and renal impairment were strongly predictive of mortality after emergent TAVR, reinforcing the logic behind staged optimization with BAV and even mechanical circulatory support in selected patients.[25]

#### 4.6. Limitations

Our study was not immune to traditional misclassification bias using databases as it relies on various codes to identify diagnoses, procedures, and outcomes. Our study was a retrospective cohort study, subject to inherent limitations of non-randomizations. There might be selection bias as the cohort may not be fully representative of the general population, as it only includes patients seeking care at participating institutes. Moreover, our study did not include patients that underwent BAV followed by TAVR during a subsequent hospitalization after 30 days, which would have provided a larger study population. Whether patients had a prior BAV outside of the time window was not specified, which could have impacted results. The study design also restricts our ability to establish causality; hence, HR was used to measure outcomes. Additionally, there might be potential variability in clinical practice and coding in different healthcare systems which may impact the generalizability of the findings.

### 5. Conclusions

For high-risk patients presenting with cardiogenic shock and severe aortic stenosis, a staged strategy using BAV can be considered as a safe and effective option for short term stabilization. These results demonstrate the BAV-TAVR staged approach does not compromise the long-term outcomes in these critically ill patients. These results reinforce the selective use of BAV as a bridge to TAVR in modern management of severe aortic stenosis with cardiogenic shock, especially for patients whose immediate candidacy for definitive therapy is uncertain.

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