

Research Article

30-Day and 1-Year Mortality after Transcatheter Aortic Valve Replacement: The Impact of Balloon Aortic Valvuloplasty as a Bridging Therapy in a Portuguese Tertiary Center

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Introduction. Since the advent and development of transcatheter aortic valve replacement (TAVR) in the contemporary era, balloon aortic valvuloplasty (BAV) has seen renewed interest. We aimed to compare 30-day and 1-year all-cause mortality between patients submitted to BAV as a bridging therapy before definite TAVR and patients submitted directly to TAVR. **Methods.** This was an observational, retrospective study of patients who underwent TAVR between 2009 and 2022 in a tertiary center. Patients with severe aortic stenosis (SAS) who underwent TAVR without prior BAV (woBAV group) and patients who were performed TAVR with prior BAV (wBAV group) as a bridging therapy were included. Primary endpoint was all-cause mortality at 30 days and 1 year after TAVR between wBAV and woBAV groups. **Results.** 800 patients were included, of which 767 were in woBAV group and 33 were in wBAV group. 30-day all-cause mortality rate was 21% in wBAV group compared to 4.4% in woBAV (unadjusted hazard ratio [HR], 5.19; 95% confidence interval [CI], 2.3–11.7, $p < 0.001$). At 1-year, all-cause mortality rate was 27% in wBAV group compared to 12% in woBAV group (unadjusted HR, 2.55; 95% CI, 1.28–5.10, $p = 0.007$). After covariate adjustments, mortality remained significantly higher in wBAV group. **Conclusion.** This study provides valuable insights into the outcomes of patients undergoing TAVR with prior BAV as bridging therapy, as these patients had higher mortality at 30 days and 1 year compared to patients direct to TAVR.

1. Introduction

Aortic stenosis (AS) remains the predominant valvular condition among the elderly population [1].

Significant shifts in the treatment approaches for various risk populations with severe AS (SAS) have occurred over the past years, largely driven by the development of transcatheter aortic valve replacement (TAVR) [2, 3].

Balloon aortic valvuloplasty (BAV) has been used for at least 3 decades [4]. Initial experiences with BAV as an alternative to surgical options in high-risk patients demonstrated a poor survival impact which limited its utilization

[5, 6]. Nevertheless, since the widespread use and availability of TAVR in current practice, BAV utilization has risen [7, 8].

Currently, BAV may be considered as a bridge to aortic valve replacement (AVR) in hemodynamically unstable patients and as bridge to urgent or high-risk noncardiac surgery (NCS) or treatment [9, 10]. In patients with limited life expectancy, BAV may be used as palliative therapy, offering short-term symptom relief. Additionally, in cases of critically ill patients, BAV might be an option as a bridge to decision [11].

Given the contemporary practice, recognizing the patient population who would benefit the most from BAV

utilization, as well as assessing both short-term and long-term outcomes of BAV as a bridge to TAVR, is imperative for tailored clinical decisions.

Our aim was to compare 30-day and 1-year all-cause mortality between patients submitted to BAV as a bridging therapy before definite TAVR and patients submitted directly to TAVR in a real-world setting.

2. Materials and Methods

2.1. Study Design. This was a single-center, observational, retrospective study of consecutive patients who underwent TAVR between 2009 and 2022 in a tertiary care center.

2.2. Inclusion Criteria. Patients with SAS who underwent direct TAVR (woBAV group) and patients with SAS who were performed BAV before TAVR (wBAV group) were included. Patients were assigned to wBAV group if the decision to perform BAV was (1) bridge to recovery due to cardiogenic shock, pulmonary oedema, or congestive heart failure due to SAS and (2) bridge to urgent or high-risk NCS or treatment. Patients that did not perform BAV as a bridging therapy before definite TAVR were assigned to woBAV group.

2.3. Exclusion Criteria. Patients whose indication for TAVR was aortic regurgitation or valve-in-valve procedures and patients who were performed BAV but did not have a definite TAVR procedure were excluded.

3. Data Collection

Based on the center protocol, all patients who underwent TAVR have performed a transthoracic echocardiogram (TTE), a 12-lead electrocardiogram, laboratory tests, an invasive coronary angiography, and a preoperative computed tomography scan (CT scan).

Baseline clinical, laboratory, echocardiographic, CT scan, hemodynamic, and procedural data were collected retrospectively through review of clinical records. Follow-up was performed through hospital outpatient medical visits in a dedicated post-TAVR consultation and clinical records.

3.1. Statistical Analysis. Categorical variables are presented as frequencies and percentages, and continuous variables as means and standard deviations, or medians and interquartile ranges as appropriate. Normal distribution was checked using the Shapiro–Wilk test.

For bivariate analysis, an independent sample *T*-test or a Mann–Whitney test was used to compare means or medians, respectively. For categorical data, the chi-square or exact Fisher test was used as appropriate.

Kaplan–Meier survival curves were calculated for each primary endpoint using log-rank test. A crude (unadjusted) univariate Cox regression was performed to assess differences in primary endpoint between study groups. The variables that were significantly different in the bivariate analysis previously performed for baseline characteristics entered the univariate Cox regression analysis.

Subsequently, the variables that had a $p \leq 0.05$ in the univariate Cox regression entered the multivariate Cox regression model. Through a backward stepwise technique, a final model was achieved for independent variables with a $p \leq 0.05$ in the multivariate Cox regression.

IBM SPSS Statistics® (version 26) was used for statistical purposes. A p value ≤ 0.05 was considered significant.

3.2. Endpoints. The primary endpoint was all-cause mortality at 30 days and 1 year after TAVR, between patients who performed BAV as bridging therapy before definite TAVR and those who did not have BAV preceding TAVR.

4. Results

A total of 800 patients met the inclusion criteria and entered the analysis. During the study period, 767 (96%) patients underwent TAVR without previous BAV (woBAV group), and 33 (4%) patients underwent BAV prior to definite TAVR (wBAV group). In this subgroup of patients, indication for BAV was bridge to recovery in 79%, the median time to definite TAVR was 172 days, and there was a significant reduction from peak-to-peak gradient measured invasively (59 ± 26 mmHg before BAV versus 27 ± 14 after BAV, 95% confidence interval [95% CI], 24–40, $p < 0.001$) (Table 1).

Table 2 depicts the baseline demographic and clinical characteristics of the two study groups.

In the overall population, median age was 83 [8] years, similar between groups. wBAV group had a lower percentage of male patients compared to those without BAV (27% vs 46%, $p = 0.040$, respectively).

Regarding past medical history, patients in the wBAV group had a significantly higher prevalence of atrial fibrillation (AF) when compared to those in the woBAV group (55% vs 32%, $p = 0.006$, respectively). Patients in the wBAV group had higher surgical risk as measured by EuroScore II or STS score compared to patient without prior BAV [6.9 (6.7) vs 4.1 (4.3), $p = 0.001$ and 5.5 (5.6) vs. 4.2 (3.7), $p = 0.022$, respectively]. No significant differences were observed between groups regarding clinical and laboratory data. The median aortic valve gradient was 48 [15] mmHg, and the median anatomic valve area was 0.7 (0.3) cm² in the overall study population, similar to those measured in both groups. Patients in the wBAV group had a significantly higher percentage of left ventricular ejection fraction (LVEF) <40%, compared to those in woBAV group (26% vs 10%, $p = 0.015$, respectively).

4.1. Primary Endpoint. Among patients who had BAV as a bridge to TAVR, the crude 30-day all-cause mortality rate was 21% ($n = 7$) compared to 4.4% ($n = 34$) for woBAV group. In the unadjusted univariate Cox regression, BAV preceding TAVR was associated with higher all-cause mortality (unadjusted hazard ratio [HR], 5.19; 95% confidence interval [CI], 2.3–11.7, $p < 0.001$) (Table 3). Kaplan–Meier cumulative survival curves for 30-day all-cause mortality between wBAV group and woBAV group are illustrated in Figure 1 (log-rank test, $p < 0.001$).

TABLE 1: Main characteristics of wBAV group ($n = 33$).

Indication		
Bridge to recovery	26	(79%)
Bridge to urgent or high-risk NCS or treatment	7	(21%)
Time until TAVR (days)		
Median (IQR)	172	(212)
Minimum	21	
Maximum	1051	
<30	7	(21%)
30 to 90	3	(9%)
90 to 180	9	(27%)
>180	14	(43%)
Peak-to-peak gradient before BAV (mmHg)	59	$\pm 26^*$
Peak-to-peak gradient after BAV (mmHg)	27	$\pm 14^*$
Procedure-related complications	3	(9%)
History of malignancy	8	(24%)

IQR, interquartile range; NCS, noncardiac surgery. *Mean differences assessed using a paired-sample *T*-test, $p < 0.001$.

TABLE 2: Baseline characteristics of study population.

Variable	Overall ($n = 800$)		wBAV group ($n = 33$)		woBAV group ($n = 767$)		<i>p</i> value
Age, years	83	(8)	82	(7.5)	83	(7.8)	0.492
Male gender	360	(45%)	9	(27%)	351	(46%)	0.040
Hypertension	670	(84%)	27	(82%)	646	(84%)	0.138*
Diabetes mellitus	286	(36%)	12	(36%)	275	(36%)	0.907
Active smoking	112	(14%)	4	(12%)	110	(14%)	0.542*
Coronary artery disease	334	(42%)	13	(39%)	321	(42%)	0.806
Previous MI	125	(16%)	6	(18%)	119	(16%)	0.360*
Previous CABG	107	(13%)	2	(6%)	105	(14%)	0.419*
Peripheral artery disease	127	(16%)	5	(15%)	122	(16%)	0.982
Previous stroke	85	(11%)	5	(15%)	80	(10%)	0.364*
Atrial fibrillation	263	(33%)	18	(55%)	245	(32%)	0.006
Previous pacemaker	80	(10%)	5	(15%)	75	(10%)	0.222*
Chronic lung disease	172	(22%)	5	(15%)	167	(21%)	0.615
Hemodialysis	20	(2.5%)	0	0	20	(2.6%)	0.551*
Bicuspid aortic valve	25	(3.1%)	1	(3%)	24	(3.1%)	0.342
EuroScore II	4.2	(4.6)	6.9	(6.7)	4.1	(4.3)	0.001
STS score	4.3	(3.8)	5.5	(5.6)	4.2	(3.7)	0.022
Clinical findings							
BMI, kg/m ²	27	(6)	26.7	(6.2)	26.6	(5.4)	0.983
Basal NYHA class	2.8	± 0.5	3	0	3	(1)	0.075
Hb, g/dL	11.9	± 1.8	11.4	± 1.7	11.9	± 1.8	0.087
Cr, mg/dL	1.1	(0.6)	1	(0.6)	1.1	(0.6)	0.768
GFR, mL/min/1.73 m ²	46	(12)]	41.5	(13)	47	(14)	0.227
HbA1c, %	5.7	(0.8)	5.8	(0.7)	5.7	(1)	0.814
NT-proBNP, pg/mL	1916	(3986)	2352	(13647)	1911	(3889)	0.79
Mean AG (mmHg)	48	(15)	45	(13)	48	(15)	0.832
Maximum AG (mmHg)	78	(14)	71	(36)	78	(12)	0.514
AVA (cm ²)	0.7	(0.3)	0.6	(0.35)	0.7	(0.30)	0.215
LVEF <50%	171	(22%)	10	(32%)	161	(21%)	0.156
LVEF <40%	86	(11%)	8	(26%)	78	(10%)	0.015*
AVCS	2104	(1738)	2659	(2371)	2100	(1704)	0.921

AG, aortic gradient; AVA, anatomic valve area; AVCS, aortic valve calcium score; BMI, body mass index; CABG, coronary artery bypass graft; GFR, glomerular filtration rate; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons. *Fisher's exact test was used. Statistically significant *p* values (< 0.05) are highlighted in bold.

After covariate Cox analysis, wBAV group remained associated with increased all-cause mortality at 30 days after TAVR (adjusted HR, 3.28, 95% CI, 1.67–8.73, $p = 0.001$) (Table 3).

At 1-year, all-cause mortality rate was 27% ($n = 9$) in wBAV group compared to 12% ($n = 92$) in woBAV group. In the unadjusted Cox regression, there was a significantly higher all-cause mortality in wBAV group compared to

TABLE 3: Results from univariate and multivariate Cox models at 30-day and 1-year all-cause mortality between groups.

Variables	30-day all-cause mortality				1-year all-cause mortality			
	Univariate analysis		Multivariate analysis		Univariate analysis		Multivariate analysis	
	HR	95% CI	HR	95% CI	HR	95% CI	HR	95% CI
BAV	5.19	(2.30-11.7)	3.82	(1.67-8.73)	2.55	(1.28-5.05)	1.99	(1.00-3.98)
Male	1.42	(0.75-2.69)			1.21	(0.81-1.80)		
Atrial fibrillation	2.49	(1.34-4.58)	2.05	(1.11-3.82)	2.38	(1.61-3.51)	2.03	(1.36-3.02)
EuroScore II	1.06	(1.03-1.08)	1.05	(1.02-1.08)	1.05	(1.03-1.07)	1.05	(1.03-1.07)
STS score	1.01	(1.0-1.02)			1.01	(1.002-1.02)		
LVEF <40%	1.44	(0.60-3.42)			1.88	(1.13-3.13)		

BAV, balloon aortic valvuloplasty; CI, confidence interval; HR, hazard ratio; LVEF, left ventricular ejection fraction; STS, Society of Thoracic Surgeons.

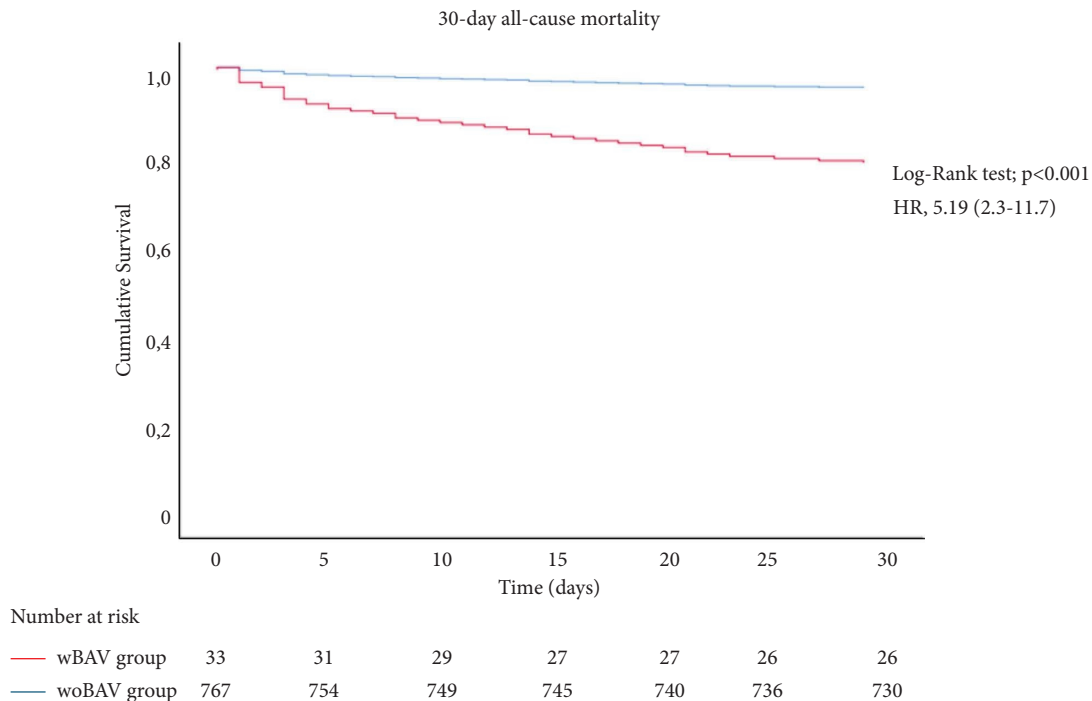


FIGURE 1: 30-day all-cause mortality Kaplan-Meier curves analysis between wBAV and woBAV groups.

woBAV group (unadjusted HR, 2.55; 95% CI, 1.28-5.10, $p = 0.007$). Cumulative survival Kaplan-Meier curves for 1-year all-cause mortality between wBAV group and woBAV group are illustrated in Figure 2 (log-rank test, $p = 0.006$).

After adjustment for other covariates, BAV preceding TAVR remained significantly associated with higher mortality when compared to TAVR procedure alone (adjusted HR, 1.99, 95% CI, 1-3.98, $p = 0.049$) (Table 3).

5. Discussion

In this study, we assessed the 30-day and 1-year all-cause mortality in a real-world setting Portuguese cohort of patients, who underwent BAV as a bridging therapy to definite TAVR versus patients who underwent direct TAVR. In the wBAV group, there was significantly higher mortality at 30 days and 1 year after TAVR, compared to woBAV group. This difference remained significant after covariates adjustments.

In our population, the median age of patients with BAV prior to TAVR was aligned with a nationwide cohort of patients in the United States, although a lower percentage of male patients (27% vs. 52%, respectively) and higher prevalence of atrial fibrillation were observed (55% vs. 45%, respectively) [16]. The same observations are true when compared with a multicentric European registry [17].

From a single-nation perspective, in our 13-year retrospective analysis, 4% of patients underwent BAV followed by TAVR as compared to 5.7% in a cohort of patients of another Portuguese tertiary center analyzed between 2013 and 2016 [18]. Still, according to data from a 14-center Portuguese National Registry of TAVR from 2007 to 2018, 2.9% of patients had bridging BAV [19]. Differences in follow-up and timing analysis of the studies, along with technique refinement and experience of operators in each center, may have contributed to the differences observed. Additionally, the number of patients undergoing BAV prior to TAVR was

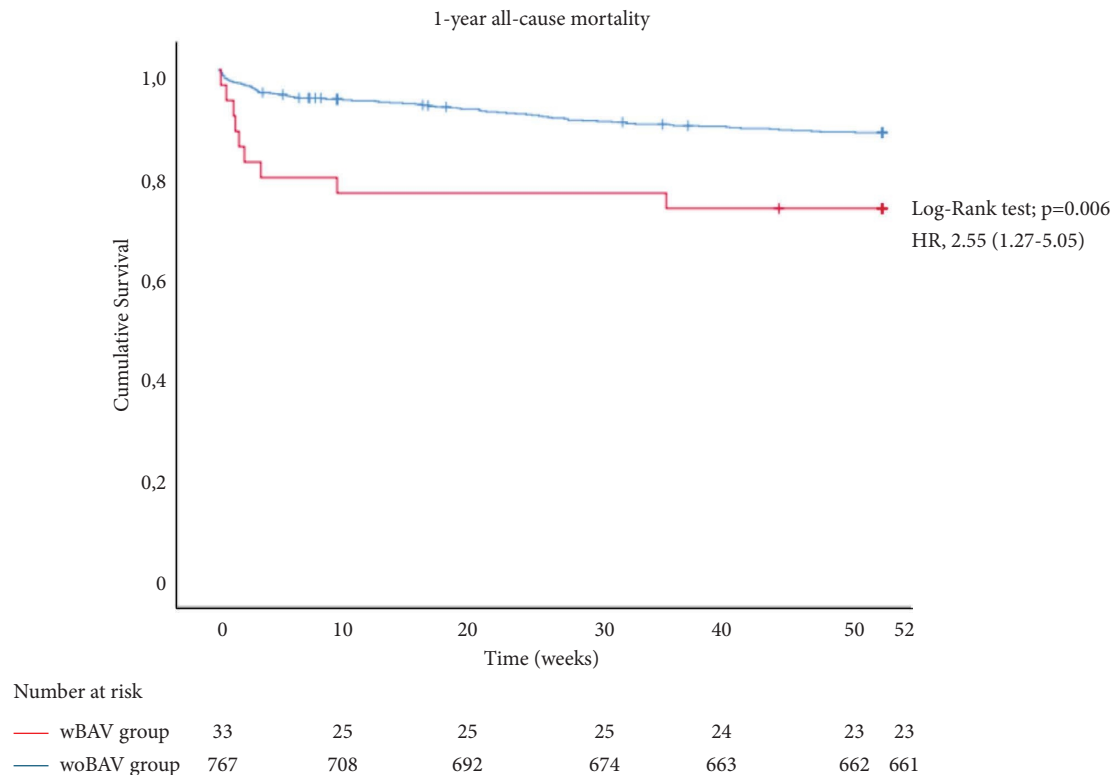


FIGURE 2: 1-year all-cause mortality Kaplan–Meier curves analysis between wBAV and woBAV groups.

below the 8.4% reported in an Italian multicenter registry [20], which reflects the current heterogeneity in patients' selection.

Regarding the primary endpoint, this cohort analysis translates a real-world experience and outcomes of patients successfully submitted to TAVR due to SAS, incorporating the impact of successful BAV as a bridging therapy. To the best of our knowledge, this is novel data potentially useful to clinical practice.

At 30-day, all-cause mortality rate was 21% in wBAV in our study, far higher than the 6.2% observed by Moretti et al. in a multicenter European registry [17]. Baseline wBAV patients' characteristics might explain this difference, as in our sample patients tended to have more comorbidities, namely, history of malignancy (24% vs 14%), previous stroke (15% vs 8%), atrial fibrillation (55% vs 17%), and lower glomerular filtration rate (41.5 vs 51 mL/min/m²). Interestingly, at 1 year after TAVR, the mortality rate was relatively the same (27%) in our cohort, as only 2 more patients died within the following months after the first 30 days, as opposed to 34% mortality rate, at the median 318-day follow-up in this European registry. This could indicate that the immediate impact on survival of such comorbidities and risk factors in the early post-TAVR period in patients previously submitted to BAV is critical.

Ben-Dor et al. reported a 22.3% 1-year mortality in patients undergoing BAV bridging to transcatheter or surgical AVR, where patient's baselines were comparable to our wBAV subgroup [21].

An important observation from our cohort of patients was that the median time to TAVR after BAV was almost 6 months. In fact, a great proportion (43%) of patients performed TAVR after 180 days as opposed to almost 30% within 90 days (Table 1). Previous research demonstrated that BAV is not necessarily associated with such delay in TAVR implantation, as most patients wait on average 90 days after bridging BAV [15, 16, 22]. Dawson et al. [23] demonstrated the benefit of BAV in improving symptoms may last at least 6 months. Nevertheless, on the long term, it is associated with valve restenosis and poorer prognosis even after aortic valve replacement. Given that these patients are baseline sicker thus needing BAV, a greater time to TAVR after bridging BAV may have had a critical negative impact on short- and long-term outcomes in our population. Kumar et al. [22] demonstrated a <18% of mortality at one year in patients submitted to TAVR within a median of 90 days after BAV compared to 29% in our sample, which highlights the importance of a timely definite strategy for SAS treatment when considering a patient for bridging BAV.

Furthermore, at 30 days, all of our patients died in-hospital due to septic shock ($n=3$) and hemorrhagic shock ($n=3$) due to procedure-related complications or pulseless electrical activity after TAVR ($n=1$). Interestingly, no cancer-related deaths were observed despite 24% of patients in the wBAV group had history of malignancy.

We believe these observations are particularly relevant for clinical practice since they translate a real-world setting

from a European national health tertiary center where long waiting lists and logistics constraints exist. In addition, it reinforces the frailty of these patients and sheds light on the importance of careful selection and timely treatments when considering a patient to bridge BAV.

Regarding patients in woBAV group, the 30-day and 1-year mortality were identical to data reported from the Portuguese National Registry of TAVR (4.4% vs 4.8% and 12 vs 11.4%, respectively) [19].

Data from a large German registry showed an equal 30-day mortality of 4.4% in patients submitted to TAVR classified as intermediate risk using the Hospital Frailty Risk score [13]. Furthermore, woBAV patients in our study died almost as much at 1 year, as the patients in the PARTNER-2A trial (12% vs 12.3%) and in the US Core Valve trial (12% vs 14.2%), which evaluated intermediate and high-risk patients, respectively [24, 25]. Accordingly, low-risk patients in TAVR trials had much lower mortality compared to our population [12, 26–28].

Given the intermediate to high-risk characteristics of our TAVR population, it appears that BAV as a bridge to recovery or bridge to urgent NCS or treatment before definite TAVR has a negative impact on short- and long-term mortality, compared to patients direct to TAVR. This translated into a 5- and 2.5-fold higher mortality of patients submitted to BAV preceding TAVR at 30-day and 1-year follow-up, respectively, in our cohort of patients.

These findings are critical to reinforce the need for careful patient selection for BAV as bridging therapy [14, 23].

In addition, acknowledging comorbidities that might also have a negative clinical impact in this clinical setting is important. In our sample, the presence of AF was particularly critical for the primary endpoint.

5.1. Limitations. This study has limitations associated with the nature of a nonrandomized, retrospective, single-center study. Also, there is a significant imbalance between groups, as the sample size in the woBAV subgroup was considerably less than woBAV subgroup, which may limit the statistical analysis and the generability of the results.

6. Conclusions

In our cohort of patients with SAS, patients that were performed BAV as a bridging therapy before definite TAVR implantation had a higher 30-day and 1-year all-cause mortality after TAVR, compared to patients without bridging BAV. The difference between groups remained significant after multivariate adjustment.

Data Availability

The clinical data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declare that there are no conflicts of interest.

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