



Mortality after radial-only balloon aortic valvuloplasty: a long-term follow-up and a bridge-to-TAVI analysis

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Abstract

Background: The benefits of distal radial balloon aortic valvuloplasty were recently reported: same efficacy as the classical femoral approach, with no vascular complications. The long-term outcomes for these patients remain unknown. **Methods:** We retrospectively analyzed the long-term mortality and the impact of TAVI in a cohort of 30 patients who underwent distal radial (DR) BAV. **Results:** The mean age was 78.3 ± 7.14 years and the median follow-up was 22.8 months. The indication for BAV was stable aortic stenosis in 70% of patients, while 23% of patients had concomitant acute heart failure symptoms and 6.6% of patients were in cardiogenic shock. A total of 16 patients (53.3%) received TAVI during follow-up after their BAV procedure while the remainder only received BAV. All-cause mortality was 20%, with only 1 death (6.3%) in the “BAV + TAVI” group compared to 5 deaths (35.7%) in the “BAV only” group ($p = 0.089$). All of the TAVI procedures were performed within 7 months after BAV. Cumulative incidence of TAVI was 40.0% at 5 months and 50.0% at 10 months. Cumulative incidence of death was 6.7% at 5 months, 13.3% at 10 months, 16.7% at 15 months, and 20.0% at 25 months. The probability of being alive without TAVI decreased from 53.3% at 5 months to 30.0% at 25 months. **Conclusion:** In the present study, we could show that half of the patients undergoing BAV eventually need TAVI, most of them within 5 months after BAV, and that BAV remains associated with high mortality after the procedure, with 35% of those undergoing isolated BAV dying during short-term follow-up.

Keywords

balloon aortic valvuloplasty, aortic stenosis, distal radial access, TAVI

Introduction

Recently, the DR-BAV (Distal Radial – Balloon Aortic Valvuloplasty) pilot study demonstrated the feasibility of performing balloon aortic valvuloplasty (BAV) through an exclusively distal radial access (DRA), reaching the efficacy endpoint (decrease in maximum and mean aortic gradient from 73 ± 22 mm Hg and 49 ± 22 mm Hg to 49 ± 19 mm Hg and 20 ± 13 mm Hg, respectively; $P < 0.001$) and reporting zero vascular complications as well as zero periprocedural major cardiovascular events [1]. Of course, a longer-term follow-up of these patients would bring more information, especially since half of the patients in this cohort received “emergency” BAV as primary indication and others were scheduled for transcatheter aortic valve implantation (TAVI), the baseline procedure being considered only stabilizing or life-saving. The radial approach in this context proved

valuable, preserving the femoral approach that may be needed in the future [1]. For BAV, large sheaths are needed, which can injure the arterial wall—a vulnerable structure in this category of patients. Thus, puncturing the radial artery at the anatomical snuffbox level to perform BAV should not be perceived as a radialist “eccentricity” but a worthwhile practice to preserve the radial artery (one of the major advantages of DRA having less radial artery occlusion rates) and for use as a secondary arterial access for TAVI [2].

After a median follow-up duration of 24 months, we conducted a retrospective evaluation of the clinical course of these patients. Furthermore, we categorized the cohort into individuals who underwent TAVI and those who did not, with the objective of examining whether this supplementary procedure influenced mortality. It is already known that BAV as an isolated intervention is inferior to TAVI and should only be indicated as a bridging intervention [3,4,5], although recently it has also gained interest as a palliative measure in many centers [6,7]. However, within the realm of cardiovascular medicine, the term “palliative” carries a more subjective and nuanced meaning compared to its usage in oncology. For instance, octogenarians and frail patients may experience a significantly enhanced clinical progression following such an intervention. The aim of this study was to analyze patients with a history of primary BAV, with or without secondary TAVI, in terms of hard clinical endpoints during a long-term follow-up (two years), starting from the initial distal radial BAV procedure.

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All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

Methods

1. Patient selection

This was an observational, registry-based study of consecutive patients with aortic stenosis (AS) who underwent distal radial BAV at a large tertiary care center (Division of Invasive Cardiology, University of Szeged, Szeged, Hungary) from 1/1/2021 to 01/11/2021 (10 months). All patients suffered from severe aortic stenosis, in different clinical stages of presentation. Severe AS was defined by a mean transvalvular gradient > 40 mmHg, and/or aortic valve area < 1.0 cm² (indexed aortic valve area < 0.6 cm²/m²) at echocardiography. Patients who underwent BAV as a part of the TAVI procedure (pre-dilatation during TAVI) were excluded.

The indication of BAV was decided within the HeartTeam of this department. As of 2020, the vascular access protocol of our catheterization laboratory has switched to ultrasound guided DRA, all transcatheter procedures being performed using this approach whenever possible. At the beginning of 2021, femoral access was also abandoned for BAV procedures, whenever there was compatibility between the diameter of the radial artery, the introducer sheath, and the dedicated valvuloplasty balloons. The radial BAV technique is described by us step-by-step elsewhere [1]. A practical table of all companies producing valvuloplasty balloons compatible with radial access is also illustrated in a report where the problem of small diameter radial arteries was solved by a simultaneous dilatation, with two balloons inserted via dual radial access [8].

The cohort was later divided into 2 groups: “BAV only” and “BAV + TAVI”. The analysis of the procedure’s feasibility and safety in terms of vascular complications and periprocedural major adverse cardiovascular events (MACEs) was recorded at the time of the BAV procedure. Afterwards, the patients were periodically followed up, their clinical evolution, all hospitalizations, relevant additional procedures, and MACEs during this interval were recorded. Patient demographics, clinical history including prior comorbidities, were collected from a standardized electronic patient record. The primary endpoint was all-cause mortality. Patients were followed up to 24 months.

The local ethics commission approved the study. Due to the retrospective nature of this study, informed consent was not available.

2. Procedure

As an indication, BAV was generally limited to the following clinical scenarios: (i) as a life-saving procedure for hemodynamically unstable patients, (ii) to facilitate urgent non-cardiac surgery, (iii) as a bridge to decision (TAVI or palliation) in patients with extra-cardiac major comorbidities, and (iv) as a diagnostic tool in patients with other potential causes for symptoms.

All the procedures were performed according to standard techniques, but adapted to the DRA (Figure 1). In case of severe coronary stenosis of primary vessels, percutaneous coronary intervention (PCI) was usually immediately performed and BAV organized in another session. During BAV, the peak-to-peak gradients were recorded using pigtail catheter in the left ventricle

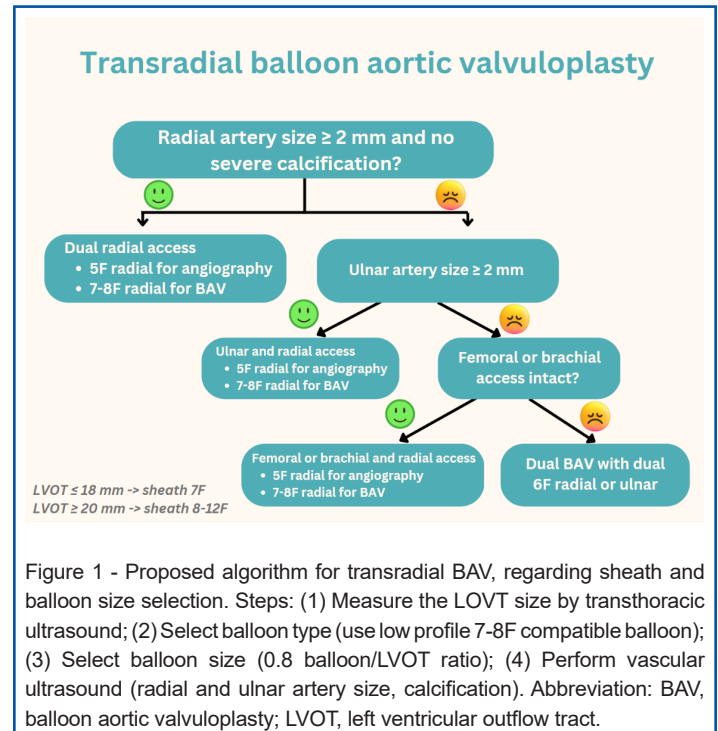


Figure 1 - Proposed algorithm for transradial BAV, regarding sheath and balloon size selection. Steps: (1) Measure the LOVT size by transthoracic ultrasound; (2) Select balloon type (use low profile 7-8F compatible balloon); (3) Select balloon size (0.8 balloon/LVOT ratio); (4) Perform vascular ultrasound (radial and ulnar artery size, calcification). Abbreviation: BAV, balloon aortic valvuloplasty; LVOT, left ventricular outflow tract.

and the secondary sheath (left hand) for the aortic pressure. The procedure was considered successful if the pre-procedural peak-to-peak gradient decreased by at least 50% after procedure. An aortogram was performed to assess aortic regurgitation only if diastolic pressures were considered abnormal.

3. Follow-up

Follow-up was obtained by trained medical personnel using direct telephone interviews and review of medical records both in-hospital and during follow-up outpatient physician visits. Echocardiographic data on aortic stenosis parameters and left ventricular systolic function prior to and following the intervention was obtained from integrated clinical records.

4. Statistical analysis

Continuous variables were evaluated for normality using the Shapiro-Wilk test and reported as mean ± standard deviation or median (interquartile range), as appropriate, while categorical variables were reported as frequencies and percentages. The “BAV only” and “BAV + TAVI” groups were compared using parametric (Student’s paired t) or non-parametric (Mann-Whitney U) tests, as appropriate, for continuous variables and the Chi-squared test for categorical variables. Given their clustered nature, the “before BAV” and “after BAV” groups were compared using McNemar’s test and continuous variables were compared by Wilcoxon signed rank test.

In this study, we performed a competing risk analysis to estimate the probabilities of three outcomes: “TAVI”, “death”, and “alive without TAVI”. We used the “cmprsk” function in R, which estimates the cumulative incidence function (CIF) of the event of interest (i.e., “TAVI”) while taking into account competing events (i.e., “death”). The

probabilities of “TAVI” and “death” were visualized using cumulative incidence curves, while the probability of being “alive without TAVI” was visualized using a survival curve. All analyses were completed with R Statistical Software (version 4.1.1, Foundation for Statistical Computing, Vienna, Austria).

Results

1. Study population

Between January 2021 and November 2021, a total of 30 patients underwent BAV. The mean age was 78.3 ± 7.14 years and 40% were male patients. The baseline demographic and clinical characteristics of the study population are presented in the Table 1. Comorbidities were present in the majority of patients (arterial hypertension 90%, diabetes mellitus 46%, chronic kidney disease 50%, dyslipidemia 56%, and atrial fibrillation 43%). The indication for BAV was stable aortic stenosis in 70% of patients, while 23% of patients had concomitant acute heart failure symptoms and 6.6% of patients were in cardiogenic shock. A total of 16 patients (53.3%) received TAVI during follow-up after their BAV procedure (i.e., “BAV + TAVI” group) while the remainder only received BAV (i.e., “BAV only” group). One patient in the “BAV only” group received additional BAV (3.3%).

2. BAV procedure

Procedural data are presented in Table 2. There was an overall peak-to-peak aortic gradient decrease from 94.6 mmHg to 40 mmHg, $p < 0.001$ (measured invasively). The efficacy of the procedure was confirmed by echocardiography, with a significant mean aortic gradient reduction from 56 mmHg to 36 mmHg, $p < 0.092$. Importantly, there was no overall aortic insufficiency aggravation ($p = 0.51$) and symptoms measured by the New York Heart Association (NYHA) functional classification were significantly improved ($p < 0.001$). Other data on BAV efficacy are illustrated in Table 3.

3. Follow-up

Median follow-up was 22.8 months (21.3–24.3) in the study population. All-cause mortality was 20%, with only 1 death (6.3%) in the “BAV + TAVI” group compared to 5 deaths (35.7%) in the “BAV only” group ($p = 0.089$). In the “BAV only” group, 35% of patients died after a median of 9.4 months. The cumulative incidence analysis is presented in Figure 2 and the accompanying estimates (including 95% confidence intervals) are shown in Table 4. Cumulative incidence of TAVI was 40% at 5 months and 50% at 10 months; no additional TAVI procedures were performed thereafter. All of the TAVI procedures were performed within 7 months after BAV. Cumulative incidence of death was 6.7% at 5 months, 13.3% at 10 months, 16.7% at 15 months, and 20% at 25 months. The probability of being alive without TAVI decreased from 53.3% at 5 months to 30% at 25 months.

Table 1 - Patient characteristics. TAVI, transcatheter aortic valve implantation; BMI, body mass index; CKD, chronic kidney disease; DM, diabetes mellitus; AHT, arterial hypertension; MI, myocardial infarction; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; balloon aortic valvuloplasty, BAV.

	All patients (N=30)	BAV only (N=14)	BAV + TAVI (N=16)	P-value
Length of follow-up, months	22.8 (21.3-24.3)	21.9 (10.4-24.2)	23.0 (22.1-24.3)	0.253
Time to TAVI, months			3.33 (2.49-4.38)	NA
Age, years	78.3±7.14	79.4±5.62	77.4±8.31	0.443
Male, n (%)	12 (40.0%)	5 (35.7%)	7 (43.8%)	0.940
BMI, kg/m ²	26.7 (23.2-29.4)	26.6 (24.0-29.3)	26.7 (22.8-29.3)	0.835
CKD, n (%)	15 (50.0%)	10 (71.4%)	5 (31.2%)	0.067
DM, n (%)	14 (46.7%)	7 (50.0%)	7 (43.8%)	1.000
AHT, n (%)	27 (90.0%)	12 (85.7%)	15 (93.8%)	0.586
Smoking, n (%)	2 (6.67%)	1 (7.14%)	1 (6.25%)	1.000
Family history of cardiovascular disease, n (%)	4 (13.3%)	3 (21.4%)	1 (6.25%)	0.315
Dyslipidemia, n (%)	17 (56.7%)	8 (57.1%)	9 (56.2%)	1.000
Previous MI, n (%)	8 (26.7%)	5 (35.7%)	3 (18.8%)	0.417
Previous CABG, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1.000
COPD, n (%)	2 (6.67%)	2 (14.3%)	0 (0.00%)	0.209
Atrial fibrillation, n (%)	13 (43.3%)	7 (50.0%)	6 (37.5%)	0.749
CVA, n (%)	2 (6.67%)	1 (7.14%)	1 (6.25%)	1.000
Permanent pacemaker, n (%)	1 (3.33%)	1 (7.14%)	0 (0.00%)	0.467
Peripheral artery disease, n (%)	14 (46.7%)	7 (50.0%)	7 (43.8%)	1.000
Initial BAV indication				0.782
Severe aortic stenosis	21 (70.0%)	11 (78.6%)	10 (62.5%)	
Severe aortic stenosis + acute heart failure	7 (23.3%)	3 (21.4%)	4 (25.0%)	
Severe aortic stenosis + cardiogenic shock	2 (6.66%)	0 (0.00%)	2 (12.5%)	
Repeat BAV	1 (3.33%)	1 (7.14%)	0 (0.00%)	0.467

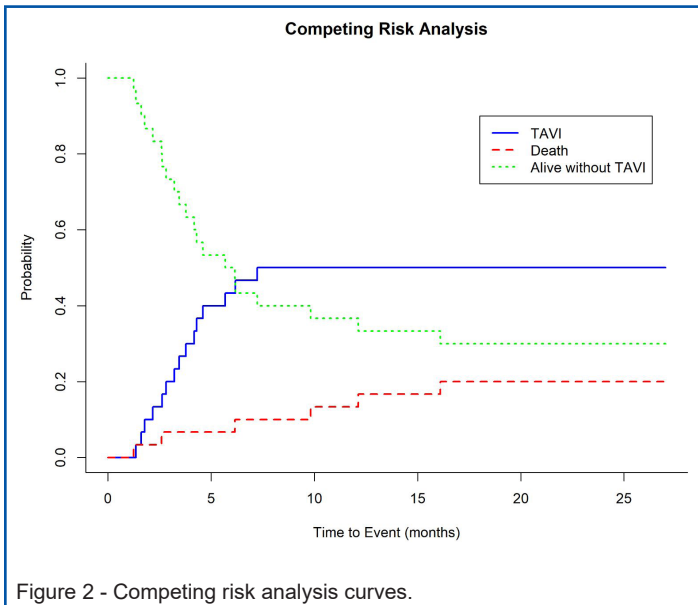


Table 2 - Procedural characteristics

Variable	Value
Sheath #1 size (French)	
5, n (%)	1 (3.33%)
6, n (%)	1 (3.33%)
7, n (%)	13 (43.3%)
8, n (%)	12 (40.0%)
9, n (%)	1 (3.33%)
10, n (%)	2 (6.67%)
Sheath #2 size (French)	
5, n (%)	3 (10.0%)
6, n (%)	24 (80.0%)
7, n (%)	2 (6.67%)
8, n (%)	1 (3.33%)
Balloon size	
14x20, n (%)	1 (3.33%)
14x40, n (%)	2 (6.67%)
16x20, n (%)	1 (3.33%)
16x40, n (%)	12 (40.0%)
18x40, n (%)	13 (43.3%)
2x12x40, n (%)	1 (3.33%)
Contrast volume, mL	82.7 (39.8)
Procedure time, min	48.2 (12.5)

Discussion

In the present study, we could show that half of the patients undergoing BAV eventually need TAVI, most of them within 5 months after BAV, and that BAV remains associated with high mortality after the procedure, with 5 out of 14 of those undergoing isolated BAV dying during short-term follow-up. Figure 2 illustrates that eventually > 60% of patients undergoing BAV eventually die or need a TAVI procedure.

This remains consistent with other reported data [9-12]. Most of our patients received TAVI in the first three to four months, an interval which is similar with other reported national registries [12]. In a larger

Table 3 - Effect of BAV. CCS, Canadian Cardiovascular Society; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; LV, left ventricle; EDD, end diastolic diameter; ESD, end systolic diameter; AI, aortic insufficiency

	Before BAV	After BAV	P-value
Symptoms scores			
Angina class (CCS)			0.025
0	16 (53.3%)	23 (76.7%)	
1	2 (6.67%)	5 (16.7%)	
2	5 (16.7%)	2 (6.67%)	
3	3 (10.0%)	0 (0.0%)	
4	4 (13.3%)	0 (0.0%)	
NYHA class			<0.001
1	0 (0.0%)	8 (26.7%)	
2	0 (0.0%)	18 (60.0%)	
3	15 (50.0%)	2 (6.67%)	
4	15 (50.0%)	2 (6.67%)	
Catheterization			
Peak-to-peak gradient across aortic valve, mmHg	94.6±31.9	40.0±15.6	<0.001
Echocardiography			
LVEF, %	47.9±17.6	50.2±13.8	0.593
LV EDD, mm	52.0 (45.2-59.0)	48.0 (44.5-58.0)	0.585
LV ESD, mm	36.7±9.60	37.2±8.21	0.773
Aortic valve peak gradient, mmHg	87.1±8.8	63.3±29.3	0.004
Aortic valve mean gradient, mmHg	56.0±20.2	36.7±14.0	0.092
AI grade			0.515
0	14 (46.6%)	3 (10%)	
1	10 (33.3%)	14 (46.6%)	
2	5 (16.6%)	12 (40%)	
3	1 (3.33%)	1 (3.33%)	

study exploring the role of BAV in critically ill patients, Kumar et al. delineated three groups of patients: critically ill on the intensive care unit (ICU), ward, and outpatient. The unadjusted 1-year mortality was high and increased stepwise between the three groups of patients (28.9%, 44.1%, 67.6%, $p < 0.001$ for the outpatient, inpatient ward, and ICU group, respectively) [13]. Conversely, the 1-year mortality in the subset of patients who underwent TAVI after BAV was similar within the three groups and was low (<18%) given the severity of the patients' illness. The research team highlighted the positive outcomes for ICU patients treated with TAVI as proof of BAV's important function in triaging patients who may benefit from the therapy. The dramatic mortality (93.3% at 1-year) among patients of the ICU group who did not undergo TAVI speaks in favor of BAV conveying favorable outcomes only when followed by TAVI [13]. This raises concerns about the viability of providing TAVI to a larger number of patients, as well as the best timing for interventions (BAV or TAVI). In this context, the radial-only BAV presents a minimally invasive method that preserves the femoral artery and could be very useful in some clinical scenarios such as stabilizing heart failure episodes or facilitating recovery or treating non-cardiac conditions before TAVI. Certainly, patients who would derive benefits from TAVI should indeed undergo the procedure. However, in the case

Table 4 - Estimates accompanying the cumulative incidence analysis (Figure 2)

Time (months)	Number at risk	TAVI, %	Death, %	Alive without TAVI, %
1	30	0.0 (0.0-0.0)	0.0 (0.0-0.0)	100 (100-100)
2	26	10.0 (2.5-23.9)	3.3 (0.2-14.8)	83.7 (75.3-99.7)
3	22	20.0 (7.9-36.0)	6.7 (1.1-19.4)	73.3 (59.1-91.0)
4	19	30.0 (14.7-46.9)	6.7 (1.1-19.4)	63.3 (48.2-83.2)
5	16	40.0 (22.4-57.0)	6.7 (1.1-19.4)	53.3 (38.2-74.5)
10	11	50.0 (30.8-66.5)	13.3 (4.0-28.3)	36.7 (22.9-58.7)
15	10	50.0 (30.8-66.5)	16.7 (5.8-32.3)	33.3 (20.1-55.3)
20	9	50.0 (30.8-66.5)	20.0 (7.8-36.2)	30.0 (17.4-51.8)
25	3	50.0 (30.8-66.5)	20.0 (7.8-36.2)	30.0 (17.4-51.8)

of severely ill patients, determining their suitability for TAVI can be challenging, and the BAV procedure does not add complexity to this decision; on the contrary, it aids in the decision-making process.

While TAVI has evolved into a more angioplasty-like routine procedure (without the presence of the anesthesia team in the operating room) that provides superior hemodynamic efficacy over BAV [14], BAV does retain some benefits. It is less expensive and more generally available, does not require contrast injection or preprocedural imagistic evaluation, can be performed with smaller sheath sizes and radial access, and can be conducted in patients who have an interim contraindication to prosthesis implantation (e.g., sepsis) [15]. In the simplest terms, BAV is currently mostly utilized as a triage tool in frail or severely ill patients when clinicians are concerned that a TAVI operation might be ineffective. Following the BAV, either the patient's condition improves and they become a candidate for TAVI, or the patient's condition worsens and a futile TAVI has been avoided. The opposing argument is that BAV-bridging strategy might lead to a delayed TAVI and could be associated with a loss of opportunity for the sickest patients. Apparently, there are no differences in outcomes between TAVI and non-TAVI centers and BAV can be performed safely even in centers without surgical back-up if the operator is experienced and has been trained in TAVI centers [16].

The palliation concept remains a pragmatic triage and treatment method. In this setting, the radial approach can keep the patient hospitalized as briefly as possible. For the frail patients with associated peripheral arterial disease that contraindicates femoral TAVI, "radial palliation" generates a contemporary indication. For femoral access, it has been recently shown that BAV may in fact be performed without heparin administration and that this resulted in fewer vascular complications [17].

Quality of life in BAV patients compares very favorably with conservatively managed patients at 6 months, while the benefit of BAV as a standalone procedure has been reported to be lost by 12 months follow-up [18,19]. The importance of symptom relief in a population with limited life expectancy due to frailty, old age, and numerous comorbidities cannot be underestimated. It should be acknowledged that BAV is a temporary treatment that reduces the need for recurring hospitalizations. BAV also proved valuable in the coronavirus disease 2019 pandemic, representing a viable therapeutic option in patients with suspected or confirmed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [20].

One of the main study's limitations was the small sample size of the study population which did not allow us to generate Kaplan-Meier survival curves and draw definitive conclusions on mortality between the BAV-only group and the BAV + TAVI group. The current study's patient population was insufficient to definitively analyze mortality as an endpoint. We also did not include in the analysis other hard clinical endpoints such as myocardial infarction or hospitalizations for acute heart failure. Lastly, the clinical progression regarding restenosis and negative clinical outcomes in patients with symptomatic severe aortic stenosis who undergo BAV as a standalone procedure is not groundbreaking, but it aligns with previous findings. The advantages derived from TAVI as the ultimate treatment are also thoroughly documented and supported by a significant body of evidence.

Conclusion

In the current study, the mortality at two years after radial-only balloon aortic valvuloplasty remains high, being mainly driven by the patient's age, comorbidities, and the lack of TAVI.

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none.

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none.

Data availability statement

The data presented in this study are available on request from the corresponding author.

Disclosures

The authors report no financial relationships or conflicts of interest regarding the content herein.

Abbreviations

BAV, balloon aortic valvuloplasty; DRA, distal radial approach; TAVI, transcatheter aortic valve implantation; MACE, major adverse cardiovascular events; PCI, percutaneous coronary intervention.

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