AsiaIntervention 2024;10:40-50

Efficacy and safety of a minimalistic balloon aortic valvuloplasty strategy in a centre without heart surgery

Matteo Bruno*, MD; Gianmarco Iannopollo, MD; Laura Sofia Cardelli, MD; Alessandro Capecchi, MD; Valerio Lanzilotti, MD; Roberto Verardi, MD; Chiara Pedone, MD; Giampiero Nobile, MD; Gianni Casella, MD

Cardiology Department, Ospedale Maggiore, Bologna, Italy and Azienda USL di Bologna, Bologna, Italy

KEYWORDS

- aortic valve stenosis
- percutaneous aortic balloon valvuloplasty

Abstract

Background: Balloon aortic valvuloplasty (BAV) is a palliative tool for patients with symptomatic severe aortic stenosis (AS) at prohibitive risk for surgery or as a bridge to surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR). BAV is traditionally performed in hospitals with onsite cardiac surgery due to its potential complications.

Aims: The aim of this study was to evaluate the safety of BAV procedures performed by trained high-volume operators in a centre without onsite surgery and to assess the effect of a minimalistic approach to reduce periprocedural complications.

Methods: From 2016 to 2021, 187 BAV procedures were performed in 174 patients. Patients were elderly (mean age: 85.0±5.4 years) and had high-risk (mean European System for Cardiac Operative Risk Evaluation score [EuroSCORE] II: 10.1±9.9) features. According to the indications, 4 cohorts were identified: 1) bridge to TAVR (n=98; 56%); 2) bridge to SAVR (n=8; 5%); 3) cardiogenic shock (n=11; 6%); and 4) palliation (n=57; 33%). BAV procedures were performed using the standard retrograde technique via femoral access in 165 patients (95%), although radial access was used in 9 patients (5%). Ultrasound-guided vascular puncture was performed in 118 patients (72%) and left ventricular pacing was administered through a stiff guidewire in 105 cases (60%).

Results: BAV safety was confirmed by 1 periprocedural death (0.6%), 1 intraprocedural stroke (0.6%), 2 major vascular complications (1%) and 9 minor vascular complications (5%). Nine cases of in-hospital mortality occurred (5%), predominantly in patients with cardiogenic shock.

Conclusions: BAV is a safe procedure that can be performed in centres without onsite cardiac surgery using a minimalistic approach that can reduce periprocedural complications.

*Corresponding author: Cardiology Department, Ospedale Maggiore, Largo Nigrisoli 2, 40133, Bologna, Italy.
E-mail: matteo.bruno@ausl.bologna.it

SUBMITTED ON 18/07/2023 - REVISION RECEIVED ON 20/09/2023 - ACCEPTED ON 06/10/2023

DOI: 10.4244/AIJ-D-23-00041

Abbreviations

ACLS	advanced cardiovascular life support
AKI	acute kidney injury
AR	aortic regurgitation
ARC	Academic Research Consortium
AS	aortic stenosis
AVA	aortic valve area
BAV	balloon aortic valvuloplasty
CKD	chronic kidney disease
COPD	chronic obstructive pulmonary disease
IABP	intra-aortic balloon pump
LVEF	left ventricular ejection fraction
LVOT	left ventricular outflow tract
MI	myocardial infarction
NYHA	New York Heart Association
ROSC	return of spontaneous circulation
SAVR	surgical aortic valve replacement
TAVR	transcatheter aortic valve replacement
TRAV	transradial aortic valvuloplasty
TTP	transvenous temporary pacemaker
US	ultrasound
VA-ECMO	venoarterial extracorporeal membrane oxygenation
VARC	Valve Academic Research Consortium

Introduction

Patients with severe symptomatic aortic stenosis (AS) are exposed to a high risk of cardiovascular death and hospitalisation for heart failure if not treated with a valve replacement[1]. Progressive ageing in Western countries has led to an increasing number of patients with severe degenerative AS, along with comorbidities, at high or prohibitive risk for surgical aortic valve replacement (SAVR). In these settings, balloon aortic valvuloplasty (BAV) has previously been performed, but its relevant rate of complications, along with its potentially life-threatening[2] and poor long-term results, has progressively limited its indications. The advent of transcatheter aortic valve replacement (TAVR) has led to a renewal of interest in BAV in recent years. Today, the procedure can be recommended not only as a destination therapy for patients excluded from TAVR but as a bridge to TAVR (or to SAVR) or as a stratification tool for certain high-risk patients who are not immediate candidates for TAVR[3]. In addition, recent data suggest that technical improvements in the BAV technique have reduced the procedural risks. Thus, today, if a minimally invasive approach is used, BAV can be performed with greater safety[4] by trained operators in centres without onsite cardiac surgery[5].

We aimed to evaluate the safety and efficacy of BAV performed by trained operators in a high-volume centre (BAV referral centre) without onsite cardiac surgery. In addition, the effects of the progressive implementation of a minimalistic approach (radial access, ultrasound-guided vascular puncture, left ventricular pacing through a stiff guidewire) on periprocedural complications are evaluated.

Methods

PATIENT POPULATION

Data on consecutive patients with severe symptomatic AS (aortic valve area [AVA] <1 cm^2) undergoing BAV at the high-volume Ospedale Maggiore Cath Lab from 1 January 2016 to 31 December 2021 were prospectively collected in a dedicated database. Patients were retrospectively subdivided into 4 cohorts according to their indications for BAV: 1) bridge to TAVR (B-TAVR); 2) bridge to SAVR (B-SAVR); 3) cardiogenic shock; and 4) palliation of symptoms in patients unsuitable for TAVR or SAVR (palliation).

The B-SAVR and the B-TAVR groups included patients initially deemed ineligible for SAVR or TAVR because of their critical condition (acute pulmonary oedema, heart failure or syncope) or who were highly symptomatic (New York Heart Association [NYHA] Class III) during the wait for TAVR or SAVR. According to the echocardiographic evaluation, patients were divided into 3 categories: high-gradient AS (mean gradient ≥40 mmHg, peak velocity ≥4.0 m/s, aortic valve area [AVA] ≤1 cm^2), low-gradient AS with reduced ejection fraction (mean gradient <40 mmHg, AVA ≤1 cm^2, left ventricular ejection fraction [LVEF] <50%), and low-gradient AS with preserved ejection fraction (mean gradient <40 mmHg, AVA ≤1 cm^2, LVEF ≥50%).

BAV PROCEDURE

All procedures were performed with the Cristal Balloon (Balt), mainly in its 20 mm diameter version; the size of the balloon length was determined using the echocardiographic measurement of the left ventricular outflow tract (LVOT). Both femoral and radial access were used. For transradial aortic valvuloplasty (TRAV), the introducer was 8 Fr, 11 cm input sheath (Medtronic), and the balloon length was 110 cm, 20 ml, compatible with the 8 Fr. In the other cases, the standard retrograde technique via the right or left femoral artery was used, with ultrasound (US)-guided femoral puncture in most cases. In these cases, an 8 to 10 Fr introducer was used.

A low-dose heparin bolus was administered after sheath insertion in all patients (40-50 IU/kg).

Rapid ventricular pacing for pulse abrogation was achieved using a 0.035-inch left ventricular support wire and, only in a few cases until 2019, using a transvenous temporary pacemaker (TTP). Balloon inflation was started as soon as pulse abrogation was observed during rapid pacing (180-200 beats/min). Thus, the balloon diameter was modulated with manual inflation in order to achieve a 1:1 balloon-to-annulus ratio, confirmed by the complete sealing of the valvular orifice and aortic pulse abrogation. In 8 cases, a 23 mm balloon was used to achieve this 1:1 balloon-to-annulus ratio. Access site closure was performed either with manual compression or with a percutaneous approach (Perclose ProGlide; Abbott).

DEFINITION AND OUTCOMES

The logistic European System for Cardiac Operative Risk Evaluation score (EuroSCORE II) was calculated for all patients.

Peripheral artery disease included a history of claudication, previous vascular surgery, or documented peripheral arterial stenosis >50%. Chronic kidney disease (CKD) was defined as a glomerular filtration rate <60 ml/min calculated by the Cockcroft-Gault formula. Chronic obstructive pulmonary disease (COPD) was identified by long-term use of bronchodilators, steroids, or oxygen. High bleeding risk was identified in patients with a haemoglobin value <11 g/dl, according to the Academic Research Consortium (ARC)[6]. Cardiogenic shock was characterised by systolic blood pressure <90 mmHg with signs of low peripheral perfusion or the necessity to administer inotropes for circulatory support. The occurrence of the following in-hospital events was recorded: death, myocardial infarction (MI), stroke, vascular complications, bleedings, acute kidney injury (AKI), acute heart failure, and severe acute aortic regurgitation. The Valve Academic Research Consortium (VARC)-2 document was used to standardise endpoint definitions[7]. Severe acute aortic regurgitation (AR) was defined as a swift and steep drop of aortic diastolic pressure, along with the rapid equilibration of left ventricular (LV) and aortic pressures, which was not present at baseline and is associated with rapid circulatory collapse.

The efficacy endpoint was a reduction in the mean invasive gradient of >30%. In-hospital and periprocedural death and complications after BAV were the safety endpoint. Follow-up was complete for all patients and used different sources: hospital files, outpatient clinics, hospital discharge records, and civil death records.

STATISTICAL ANALYSIS

Continuous variables are expressed as mean (±standard deviation [SD]) and comparisons between groups were performed with the one-way analysis of variance (ANOVA). Categorical variables were compared using Pearson's chi-square test when suitable. All tests were two-sided and statistical significance was defined as $p<0.05$. Cumulative event rates were estimated using the Kaplan-Meier method and compared by the log-rank test. The Cox proportional hazard regression method (and logistic regression analyses at 30 days and 1 year) was used to examine the association of clinical, echocardiographic, and procedural variables with mortality during follow-up. Multivariate analyses, including all variables with $p\leq0.10$ at univariate analysis, were performed to identify independent predictors of mortality at 30 days and 1 year. All analyses were carried out using the SPSS statistical software package version 24.0 (IBM). The study was conducted according to the Declaration of Helsinki.

Results

From January 2016 to December 2021, 174 patients underwent BAV at our centre. Twelve patients underwent a repeat procedure, with one patient receiving it three times; thus, the total number of procedures was 187 **(Figure 1)**. Patients were 85.0±5.4 years old and had a high risk score (EuroSCORE II 10.1±9.9) **(Table 1)**. Ten patients had previously undergone BAV. Typical clinical presentations were heart failure (n=124; 71%) or syncope (n=42; 24%).

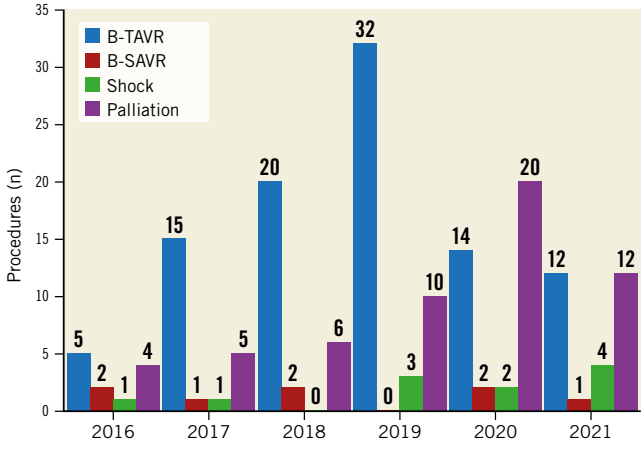


Figure 1. *Number of balloon aortic valvuloplasty procedures per year according to indication. B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement*

According to the indications, we identified 4 cohorts: 1) bridge to TAVR (n=98; 56%); 2) cardiogenic shock (n=11; 6%); 3) bridge to SAVR (n=8; 5%); and 4) palliation (n=57; 33%). Most patients had high-gradient aortic stenosis (mean gradient ≥40 mmHg, peak velocity ≥4.0 m/s, AVA ≤1 cm^2 or ≤0.6 cm^2/m^2) **(Table 2)**[8].

Femoral access was standard **(Table 3)**, with US-guided puncture of the femoral artery itself implemented in 2019. In a patient with significant peripheral chronic obliterative arteriopathy and with no other access, a US-guided brachial puncture was performed.

In order to reduce vascular complications in cases with an additional access site, rapid ventricular pacing for pulse abrogation was performed using a 0.035-inch left ventricular support wire. A few cases had a transvenous temporary pacemaker (TTP) in place (until 2019), mostly with right bundle branch block on a standard electrocardiogram (ECG).

The efficacy endpoint, a reduction of the invasive peak-to-peak gradient ≥30%, was achieved in 93% of cases **(Figure 2**, **Figure 3A**, **Figure 3B**, **Central illustration).** Invasive maximum and mean gradients were reduced from 56±24 mmHg and 39±17 mmHg to 28±15 mmHg and 20±12 mmHg, respectively. A statistically significant improvement from baseline was noted in the invasive peak-to-peak gradient in all groups (p=0.007) **(Table 3)**. In-hospital mortality was 5% and occurred predominantly in patients with cardiogenic shock that had received an emergent, rescue BAV **(Table 4)**. There was only one periprocedural death, which was probably due to aortic annulus rupture. Vascular complications occurred primarily before 2019. After this date, the routine use of US-guided puncture reduced vascular complication rates.

Clinical outcomes are listed in **Table 5**. One-year mortality was 28.7%: the highest mortality was in the shock group (73%) and the lowest in the B-TAVR group (18%). The incidence of 1-year death or hospitalisation for heart failure (HF) was lower in the B-TAVR group. Cumulative rates of clinical outcomes

Table 1. Demographics and baseline characteristics.

Characteristic	All patients (n=174)	B-TAVR (n=98)	B-SAVR (n=8)	Shock (n=11)	Palliation (n=57)	*p*-value*
Age, years	85.0±5.4	85.0±4.4	74.9±7.7	83.3±5.6	86.9±5.0	<0.001
Male sex	45.4 (79)	50.0 (49)	25.0 (2)	45.5 (5)	40.4 (23)	0.456
BMI, kg/m^2	26.2±4.3	25.8±4.0	28.3±4.8	27.0±6.0	26.5±4.5	0.316
Diabetes	25.3 (44)	19.4 (19)	37.5 (3)	45.5 (5)	29.8 (17)	0.068
Dyslipidaemia	51.1 (89)	51.0 (50)	75.0 (6)	63.6 (7)	45.6 (26)	0.347
Hypertension	82.2 (143)	83.7 (82)	75.0 (6)	72.7 (8)	82.5 (47)	0.823
Cancer	26.4 (46)	27.6 (27)	25.0 (2)	0.0 (0)	29.8 (17)	0.218
COPD	23.0 (40)	20.4 (20)	12.5 (1)	36.4 (4)	26.3 (15)	0.412
Peripheral arteriopathy	46.0 (80)	49 (48)	25.0 (2)	45.5 (5)	43.9 (25)	0.637
Neurological dysfunction	15.5 (27)	15.3 (15)	0.0 (0)	9.1 (1)	19.3 (11)	0.634
Atrial fibrillation	37.9 (66)	34.7 (34)	0.0 (0)	45.5 (5)	47.4 (27)	0.028
Pacemaker	7.5 (13)	6.1 (6)	0.0 (0)	9.1 (1)	10.5 (6)	0.523
Prior MI	23 (40)	18.4 (18)	25.0 (2)	36.4 (4)	28.1 (16)	0.237
Prior revascularisation PCI or CABG	19.5 (34)	18.4 (18)	12.5 (1)	36.4 (4)	19.3 (11)	0.539
Prior CVA	11.5 (20)	13.3 (13)	0.0 (0)	9.1 (1)	10.5 (6)	0.909
Prior BAV	5.2 (9)	5.1 (5)	0.0 (0)	0.0 (0)	7.0 (4)	0.901
Anaemia/Hb ≤11 g/dl	29.9 (52)	23.5 (23)	25.0 (2)	36.4 (4)	40.4 (23)	0.145
CKD (GFR <60ml/min)	59.2 (103)	46.9 (46)	0.0 (0)	100 (11)	80.7 (46)	<0.001
Dialysis	1.1 (2)	1.0 (1)	0.0 (0)	0.0 (0)	1.8 (1)	0.998
EF ≤35%	19.0 (33)	12.2 (12)	12.5 (1)	36.4 (4)	28.1 (16)	0.029
Stable angina	8.6 (15)	10.2 (10)	0.0 (0)	9.1 (1)	7.0 (4)	0.957
Acute coronary syndrome	14.9 (26)	13.3 (13)	12.5 (1)	27.3 (3)	15.8 (9)	0.588
NYHA III-IV	71.3 (124)	67.3 (66)	75.0 (6)	72.7 (8)	77.2 (44)	0.629
Syncope	24.1 (42)	23.5 (23)	37.5 (3)	18.2 (2)	24.6 (14)	0.804
Cardiogenic shock	5.7 (10)	1.0 (1)	0.0 (0)	72.7 (8)	1.8 (1)	<0.001
EuroSCORE II, %	10.1±9.9	7.7±6.1	2.5±1.7	26.3±20.3	12.5±10.0	<0.001
Porcelain aorta	2.3 (4)	3.1 (3)	0.0 (0)	0.0 (0)	1.8 (1)	0.998

Data are shown as mean±SD for continuous variables and % (absolute numbers) for dichotomous variables. *for comparison between subgroups.
BAV: balloon aortic valvuloplasty; BMI: body mass index; B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement; CABG: coronary artery bypass graft surgery; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; CVA: cerebrovascular accident; EF: ejection fraction; EuroSCORE: European System for Cardiac Operative Risk Evaluation; GFR: glomerular filtration rate; Hb: haemoglobin; MI: myocardial infarction; NYHA: New York Heart Association Functional Class; PCI: percutaneous coronary intervention; SD: standard deviation

at 40-month follow-up are shown in **Figure 4A** and **Figure 4B**. Variables associated with mortality during BAV follow-up are listed in **Table 6**.

Safety was confirmed, even in repeat procedures. Repeat BAV was not associated with a higher risk of death (odds ratio [OR] 1.176, 95% CI: 0.364-3.800; p=0.787) or vascular complications (no repeat procedure had any vascular complication).

Discussion

The main findings of our study are as follows:

1. BAV can be safely performed in centres without onsite heart surgery, with few procedural complications and low in-hospital mortality. Even repeat procedures are safe.

2. One-year mortality is higher for patients with BAV as palliation or with shock at presentation.

3. The risk of rehospitalisation is higher in patients who do not proceed to aortic valve replacement.

Balloon aortic valvuloplasty was first proposed in 1986 by Cribier as an alternative to SAVR in patients with severe senile aortic stenosis. Subsequent studies confirmed the utility of stand-alone BAV in improving symptoms but showed no effect on survival[9]. In addition, the BAV procedure was associated with significant morbidity and mortality. Therefore, after an initial peak in the 1990s, the utilisation of BAV decreased dramatically, being reserved for palliative indications. The introduction of TAVR has renewed interest in BAV, mainly due to the

Table 2. Echocardiographic parameters before and after balloon aortic valvuloplasty.

Pre-BAV (n=174)	All patients (n=174)	B-TAVR (n=98)	B-SAVR (n=8)	Shock (n=11)	Palliation (n=57)	*p*-value*
AVA, cm^2	0.6±0.2	0.6±0.1	0.7±0.1	0.6±0.2	0.7±0.2	0.101
Average transvalvular gradient, mmHg	51.1±16.7	54.9±14.9	65.7±20.2	42.0±22.0	43.6±14.9	<0.001
Peak-to-peak transvalvular gradient, mmHg	81.1±25.9	86.6±24.8	92.2±31.4	64.7±33.0	72.4±22.5	0.001
Aortic regurgitation						
Moderate/severe	0.6 (1)	0 (0)	0 (0)	0 (0)	1.8 (1)	0.446
Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
Mitral valve regurgitation						
Moderate/severe	10.9 (19)	9.2 (9)	12.5 (1)	9.1 (1)	14.0 (8)	0.833
Severe	3.4 (6)	2.0 (2)	0 (0)	18.2 (2)	3.5 (2)	0.107
LVEF, %	49.4±13.9	53.1±12.6	51.7±18.7	35.6±12.5	45.4±12.9	<0.001
Post-BAV (n=126)						
AVA, cm^2	0.8±0.2	0.8±0.2	0.9±0.1	0.5±0.1	0.8±0.2	0.010
Average transvalvular gradient, mmHg	38.3±13.5	40.5±12.9	38.6±12.8	39.1±25.1	33.7±11.2	0.096
Peak-to-peak transvalvular gradient, mmHg	62.9±21.1	67.3±20.3	55.0±19.0	57.5±39.6	56.7±17.7	0.049
Aortic regurgitation						
Moderate/severe	0.6 (1)	0 (0)	0 (0)	0 (0)	1.8 (1)	0.427
Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
Mitral valve regurgitation						
Moderate/severe	5.2 (9)	2.0 (2)	0 (0)	18.2 (2)	8.8 (5)	0.027
Severe	1.7 (3)	1.0 (1)	0 (0)	9.1 (1)	1.8 (1)	0.304
LVEF, %	48.3±13.7	51.6±12.9	36.7±15.1	29.2±5.7	45.7±13.0	0.002

Data are shown as mean±SD for continuous variables and % (absolute numbers) for dichotomous variables. *for comparison between subgroups.
AVA: aortic valve area; BAV: balloon aortic valvuloplasty; B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement; LVEF: left ventricular ejection fraction; SD: standard deviation

Table 3. Procedural and haemodynamic data.

	All patients (n=174)	B-TAVR (n=98)	B-SAVR (n=8)	Shock (n=11)	Palliation (n=57)	*p*-value*
Balloon size, mm	19.5±1.2	19.4±1.2	20.5±1.7	19.1±1.0	19.5±1.3	0.069
Peak-to-peak gradient pre-BAV, mmHg	55.9±23.9	60.4±24.1	67.1±22.6	52.1±33.3	46.9±18.6	0.003
Peak-to-peak gradient post-BAV, mmHg	27.7±14.5	30.1±14.8	30.6±13.1	24.3±20.2	23.8±11.7	0.060
Average gradient pre-BAV, mmHg	39.3±16.7	42.5±16.7	48.1±18.5	34.3±23.3	33.0±13.1	0.004
Average gradient post-BAV, mmHg	19.8±11.7	21.2±10.7	20.1±9.5	17.2±17.1	16.2±9.2	0.043
TTP	13.8 (24)	17.3 (17)	25.0 (2)	9.1 (1)	7.0 (4)	0.168
LV guidewire pacing	60.3 (105)	66.3 (65)	50.0 (4)	9.1 (1)	61.4 (35)	0.002
US-guided femoral puncture	72 (118)	65.3 (64)	50.0 (4)	72.7 (8)	73.7 (42)	0.486
Radial approach	5.2 (9)	6.1 (6)	0.0 (0)	9.1 (1)	3.5 (2)	0.689
PCI	14.4 (25)	19.4 (19)	25.0 (2)	9.1 (1)	5.3 (3)	0.047
Improvement from baseline peak-to-peak gradient	28.5±13.6	30.6±13.8	36.5±16.7	27.8±16.1	23.6±10.6	0.007

Data are shown as mean±SD for continuous variables and % (absolute numbers) for dichotomous variables. *for comparison between subgroups.
BAV: balloon aortic valvuloplasty; B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement; LV: left ventricular; PCI: percutaneous coronary intervention; SD: standard deviation; TTP: transvenous temporary pacemaker; US: ultrasound

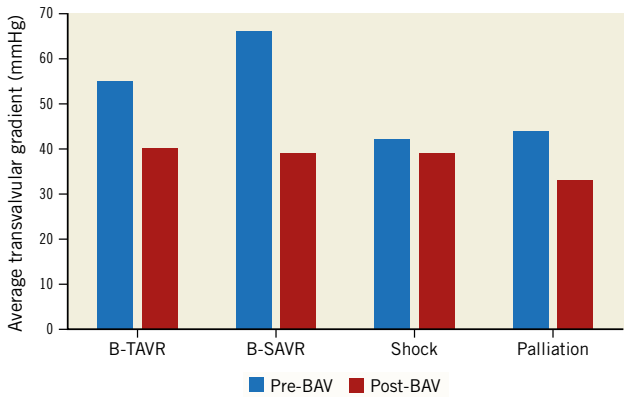


Figure 2. *Average transvalvular gradient: echocardiographic assessment. BAV: balloon aortic valvuloplasty; B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement*

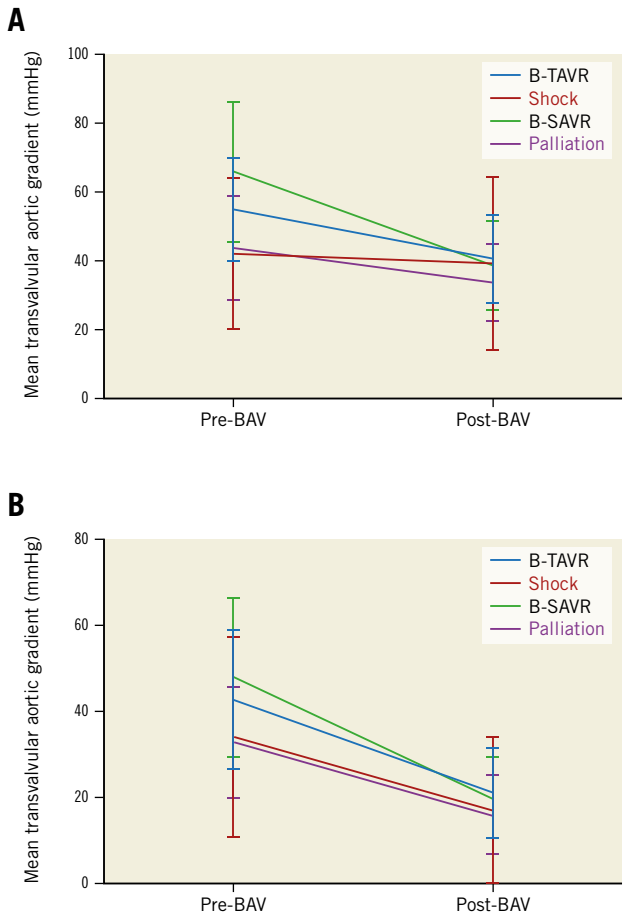


Figure 3. *Reduction of mean transvalvular gradient after BAV. A) Reduction of mean transvalvular gradient (mean value and standard deviation) after BAV; echocardiographic assessment. B) Reduction of mean transvalvular gradient (mean value and standard deviation) after BAV; invasive gradient. BAV: balloon aortic valvuloplasty; B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement*

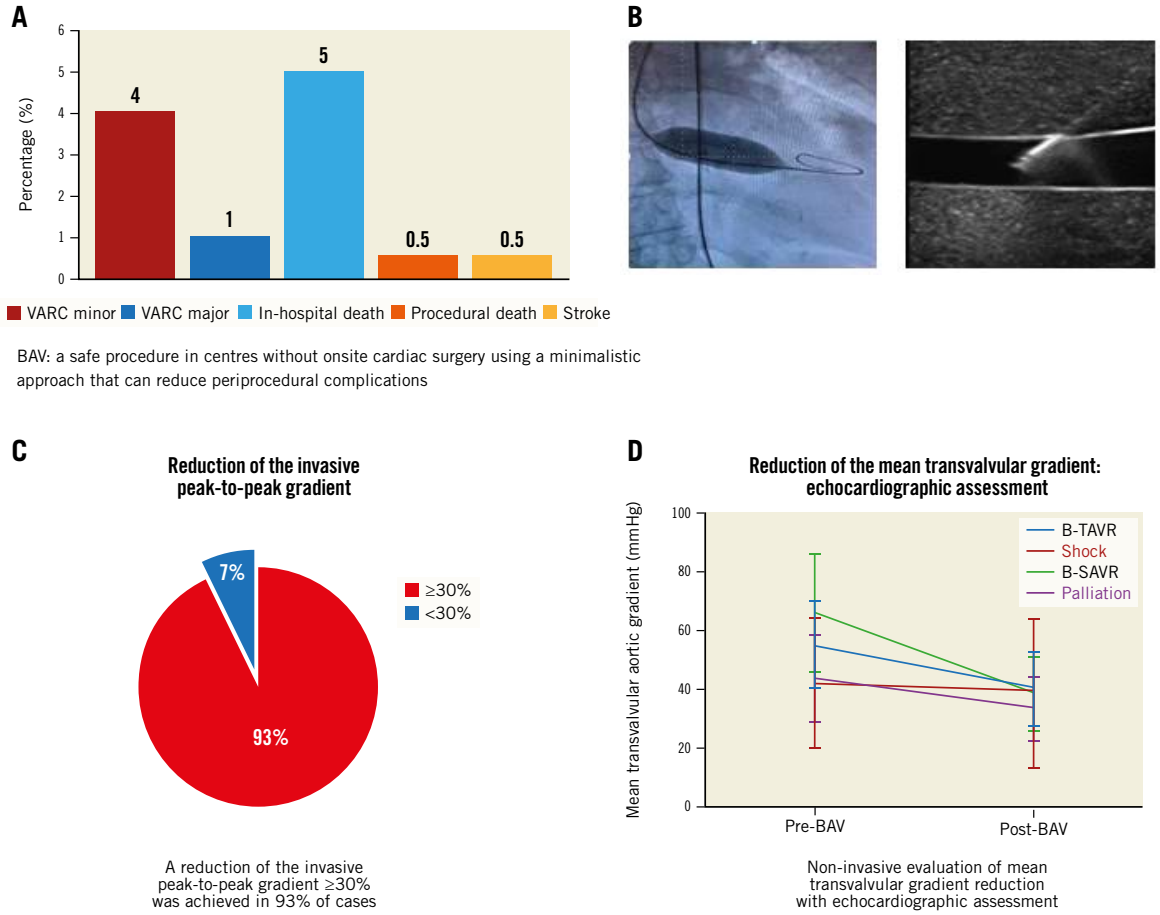
increased referral of elderly patients with multiple risk factors who were previously untreated. Remarkably, a significant proportion of patients remain without any option of definitive treatment. For most of these remaining no-option patients, BAV can offer significant immediate haemodynamic and clinical improvement with an improved quality of life. It is a low-cost and relatively safe procedure in experienced hands. It can be performed by trained operators in centres without onsite cardiac surgery using a minimalistic approach (radial access or ultrasound-guided vascular puncture, left ventricular pacing through a stiff guidewire) that can reduce periprocedural complications. In our cohort, the rates of periprocedural adverse events were lower compared to earlier registries[2] and comparable to that of centres with onsite surgery[10]. Additionally, there were no cases of acute severe aortic regurgitation. If this occurs, manipulating a pigtail catheter reinforced with a stiff guidewire can remobilise the blocked cusp, often a cause of AR[11]. In case of any life-threatening developments, our team was equipped and trained to perform lifesaving manoeuvres (e.g., pericardiocentesis, blood transfusion, advanced cardiovascular life support [ACLS], intra-aortic balloon pump [IABP], Impella [Abiomed], and venoarterial extracorporeal membrane oxygenation [VA-ECMO] in selected cases); they were based a short distance (5 km) away from the referral cardiothoracic centre with fast-track transport access. In our cohort, there was only a single periprocedural death, a 91-year-old woman admitted for acute pulmonary oedema. During the BAV procedure, balloon rupture occurred with subsequent pulseless electrical activity; no pericardial effusion was detected at echocardiography. Despite a transient return of spontaneous circulation (ROSC) after ACLS manoeuvres and IABP implantation, the patient died in the intensive care unit. The probable diagnosis was annular rupture, but this was unconfirmed since an autopsy was not performed. However, despite the nearby cardiothoracic centre (5 km away), the chance of survival in this specific case would have been low even if the event had happened in a heart valve centre. The incidence of stroke was very low (0.5%), suggesting that major embolisation of debris from the aortic valve is a rare phenomenon. The use of left ventricular pacing through a stiff guidewire (sparing a venous puncture for a temporary pacemaker), radial access and the routine use of US-guided femoral puncture from 2019 onwards has led to a proportional reduction of vascular complications.

The 1-year incidence of death or rehospitalisation was lower in the TAVR group, but numbers were still high. These data may be explained by the fact that only 56% of B-TAVR patients proceeded to intervention **(Figure 5)**. This result is not surprising: in a recent multicentre BAV registry, only 29% patients referred for TAVR underwent percutaneous replacement[3].

Patients who are candidates for aortic valve replacement after successful BAV are discussed by the Heart Team and listed for referral to a heart valve centre. Priority is given to those with a worsening of clinical condition or readmission for heart failure.

AsiaIntervention

CENTRAL ILLUSTRATION Efficacy and safety of a minimalistic balloon aortic valvuloplasty strategy in centres without heart surgery.



BAV: a safe procedure in centres without onsite cardiac surgery using a minimalistic approach that can reduce periprocedural complications

A reduction of the invasive peak-to-peak gradient ≥30% was achieved in 93% of cases

Non-invasive evaluation of mean transvalvular gradient reduction with echocardiographic assessment

A) Periprocedural complications. B) Balloon inflation in aortic valvuloplasty, left panel and ultrasound-guided vascular puncture, right panel. C) Reduction of the invasive peak-to-peak gradient. D) Non-invasive evaluation of mean transvalvular gradient reduction. BAV: ballon aortic valvuloplasty; B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement; VARC: Valve Academic Research Consortium

Table 4. In-hospital outcomes.

	All patients (n=174)	B-TAVR (n=98)	B-SAVR (n=8)	Shock (n=11)	Palliation (n=57)	*p*-value*
In-hospital death	5.2 (9)	0 (0)	0 (0)	63.6 (7)	3.5 (2)	<0.001
Periprocedural death	0.6 (1)	0 (0)	0 (0)	0 (0)	1.8 (1)	0.998
Acute myocardial infarction	1.1 (2)	1.0 (1)	0 (0)	9.1 (1)	0 (0)	0.199
Stroke	0.6 (1)	1.0 (1)	0 (0)	0 (0)	0 (0)	0.998
Major vascular complications¶	1.1 (2)	1.0 (1)	0 (0)	0 (0)	1.8 (1)	0.938
Minor vascular complications¶	5.2 (9)	6.1 (6)	0 (0)	0 (0)	5.3 (3)	0.998
Life-threatening/disabling bleeding¶	0.6 (1)	0 (0)	0 (0)	0 (0)	1.8 (1)	0.430
Major bleeding¶	2.9 (5)	2.0 (2)	0 (0)	9.1 (1)	3.5 (2)	0.448
Minor bleeding¶	5.2 (9)	6.1 (6)	0 (0)	0 (0)	5.3 (3)	0.999
Acute kidney injury¶	3.4 (6)	1.0 (1)	0 (0)	27.3 (3)	3.5 (2)	0.004

Data are shown as % (absolute numbers). *for comparison between subgroups. ¶according to Valve Academic Research Consortium-2 classification. B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement

Table 5. Cumulative clinical outcomes during follow-up.

	All patients (n=174)	B-TAVR (n=98)	B-SAVR (n=8)	Shock (n=11)	Palliation (n=57)	*p*-value*
Repeat BAV at 1 year	4.6 (8)	5.1 (5)	0 (0)	0 (0)	5.3 (3)	0.998
Death at 30 days	7.5 (13)	3.1 (3)	0 (0)	63.6 (7)	5.3 (3)	<0.001
Death at 1 year	28.7 (50)	18.4 (18)	37.5 (3)	72.7 (8)	36.8 (21)	<0.001
Hospitalisation for HF at 1 year	21.2 (36)	21.9 (21)	25.0 (2)	0 (0)	23.2 (13)	0.390
Death or hospitalisation for HF at 1 year	39.3 (68)	30.9 (30)	50.0 (4)	72.7 (8)	45.6 (26)	0.023

Data are shown as % (absolute numbers). *for comparison between subgroups. BAV: balloon aortic valvuloplasty; B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement; HF: heart failure

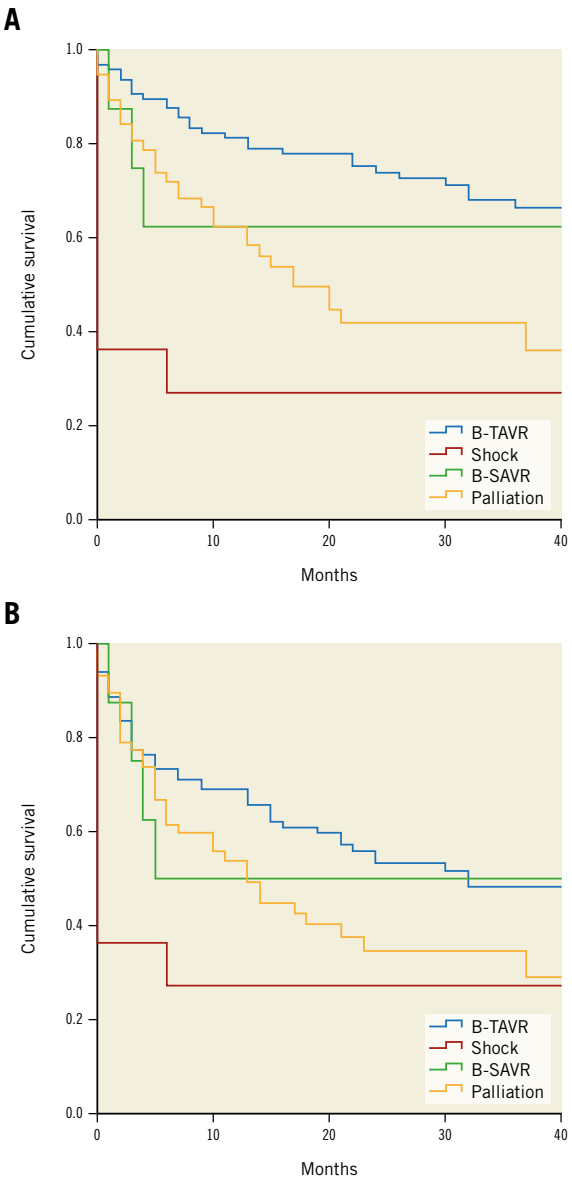


Figure 4. *Clinical outcomes after BAV. A) Clinical outcomes after BAV for different indications. B) Clinical outcomes: cumulative survival or freedom from rehospitalisation for heart failure. B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement*

The waiting time for SAVR was on average 92±62 days (median 74 days [interquartile range {IQR} 53-142]). Even for patients proceeding to TAVR, it is already known that time on the waiting list is associated with significant morbidity and mortality. In our cohort, the average delay between BAV and TAVR was 156±120 days (median: 136 days [IQR 88-193]).

The risk of death whilst waiting for intervention in routine clinical practice ranges from 2.7% to 14.0%[12]. In an important retrospective study, the cumulative probability of waiting list mortality and heart failure hospitalisation at 80 days were 2% and 12%, respectively, with a relatively constant increase in events according to increased waiting time[13]. In addition, patients classified as high risk for valve surgery have a higher waiting list mortality prior to either surgical or transcatheter aortic valve intervention than those classified as low risk. In our study, 27% of patients (n=26) in the B-TAVR group who were due to be treated died before intervention, and 27% (n=26) were admitted again for HF before intervention.

Furthermore, in the case of patients with an urgent indication for BAV due to their critical condition, it is interesting that if they overcame the acute phase and proceeded to definitive aortic valve treatment, these patients then survived up to 40 months free from readmission for heart failure.

In the palliation group, 8 patients' (14%) indication changed to TAVR, in line with a previous report[3]. In the B-SAVR group, only 3 patients (38%) proceeded to aortic valve replacement; 2 patients' (25%) indication changed to TAVR after discussion in the Heart Team. Even these data are not surprising[3].

Nowadays, exponential growth in TAVR demand could overwhelm the capacity of interventional hub centres, resulting in inadequate access to care and prolonged waiting list times compared to currently available resources. A clinical evaluation 1 month after discharge could be useful to assign a targeted priority queue after BAV. In the future, the best solution would reduce the time to intervention. This point could be addressed by switching high-risk patients, already excluded from surgical intervention, to TAVR in hospitals without an onsite cardiac surgery centre. In this new scenario, other therapeutic strategies,

Table 6. Predictors of mortality during follow-up after standalone BAV.

	HR	95% CI		*p*-value
		Lower	Upper	
30 days				
Univariate analysis				
Diabetes	6.296	1.895	20.915	0.003
CKD	4.965	1.088	22.663	0.039
Shock	21.780	7.203	65.860	<0.001
EuroSCORE II	1.111	1.071	1.151	<0.001
Average gradient pre-BAV <40 mmHg	6.505	1.904	22.232	0.003
Mitral valve regurgitation >3+	3.575	1.169	10.933	0.025
LVEF ≤35%	5.463	1.835	16.263	0.002
Guidewire pacing	0.187	0.052	0.681	0.011
Multivariate Cox analysis				
Diabetes	7.269	1.222	43.244	0.029
CKD	68.789	3.407	1,388.693	0.006
Shock	13.842	1.746	109.747	0.013
EuroSCORE II	1.117	1.054	1.184	<0.001
Guidewire pacing	0.122	0.021	0.706	0.019
	HR	**95% CI**		***p*-value**
		Lower	**Upper**	
1 year				
Univariate analysis				
Shock	5.417	2.426	12.095	<0.001
Diabetes	2.923	1.663	5.136	<0.001
Atrial fibrillation	1.838	1.050	3.220	0.033
Previous MI	2.509	1.411	4.460	0.002
EuroSCORE II	1.070	1.045	1.0895	<0.001
CKD	1.783	0.994	3.198	0.053
Average gradient pre-BAV <40 mmHg	2.977	1.653	5.361	<0.001
Mitral valve regurgitation >3+	2.008	1.049	3.845	0.035
LVEF ≤35%	2.838	1.579	5.101	<0.001
Multivariate Cox analysis				
EuroSCORE II	1.043	1.010	1.076	0.010
Diabetes	2.670	1.432	4.978	0.002
Previous MI	2.894	1.513	5.539	0.001
LVEF ≤35%	1.843	0.958	3.547	0.067
Mitral valve regurgitation >3+	2.085	1.006	4.323	0.048

BAV: balloon aortic valvuloplasty; CI: confidence interval; CKD: chronic kidney disease; EuroSCORE: European System for Cardiac Operative Risk Evaluation; HR: hazard ratio; LVEF: left ventricular ejection fraction; MI: myocardial infarction

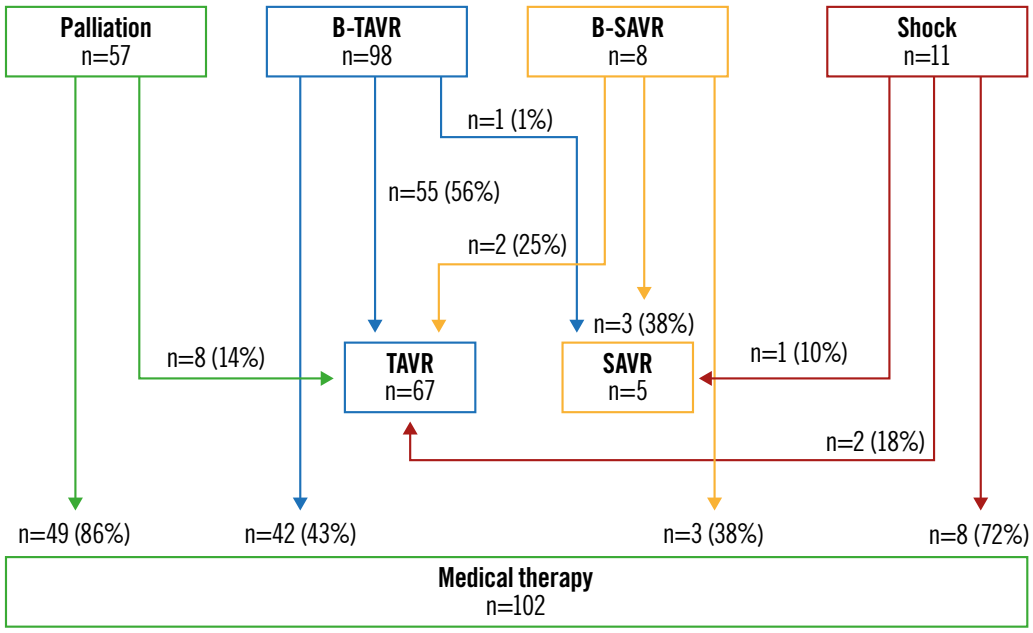


Figure 5. *Actual intervention based on the initial indication group. B-SAVR: bridge to surgical aortic valve replacement; B-TAVR: bridge to transcatheter aortic valve replacement; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement*

such as direct TAVR for selected patients in centres with onsite cardiac surgery, could further reduce the time to intervention and costs.

Limitations

Data were collected retrospectively. It has therefore not been possible to identify if 16 patients might have undergone subsequent TAVR or SAVR in a different city or country.

Conclusions

The emerging indication for TAVR in high-risk patients has led to increasing BAV numbers. BAV is a safe and effective procedure that can be performed by trained operators in high-volume centres without onsite cardiac surgery. A minimalistic approach could reduce periprocedural complications. Despite its safety, long-term clinical outcomes remain disappointing, and a definitive treatment solution must be found without delay.

Impact on daily practice

A minimalistic aortic valvuloplasty strategy, reducing periprocedural complications, may facilitate an increase in balloon aortic valvuloplasty (BAV) procedures for symptomatic patients with severe aortic stenosis even in centres without cardiac surgery. This strategy can promptly relieve patient symptoms until definitive treatment is possible.

Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Maganti K, Rigolin VH, Sarano ME, Bonow RO. Valvular heart disease: diagnosis and management. *Mayo Clin Proc.* 2010;85:483-500.

2. Alkhouli M, Zack CJ, Sarraf M, Bashir R, Nishimura RA, Eleid MF, Nkomo VT, Sandhu GS, Gulati R, Greason KL, Holmes DR, Rihal CS. Morbidity and Mortality Associated With Balloon Aortic Valvuloplasty: A National Perspective. *Circ Cardiovasc Interv.* 2017;10:e004481.

3. Moretti C, Chandran S, Vervueren PL, D'Ascenzo F, Barbanti M, Weerackody R, Boccuzzi G, Lee DH, de la Torre Hernandez J, Omedè P, Nijenhuis V, Igbineweka N, Lim P, ten Berg, Carriè D, Hildick-Smith D, Gulino S, Cannata S, Gargiulo G, Tamburino C, Conrotto F, Meynet I, Quadri G, Marangoni L, Taha S, Biondi-Zoccai G, Salizzoni S, Marra S, Gaita F. Outcomes of Patients Undergoing Balloon Aortic Valvuloplasty in the TAVI Era: A Multicenter Registry. *J Invasive Cardiol.* 2015;27:547-53.

4. Tumscitz C, Di Cesare A, Balducelli M, Piva T, Santarelli A, Saia F, Tarantino F, Preti G, Picchi A, Rolfo C, Attisano T, Colonna G, De Iaco G, Parodi G, Di Marco M, Cerrato E, Pierini S, Fileti L, Cavazza C, Dall'Ara G, Govoni B, Mantovani G, Serenelli M, Penzo C, Tebaldi M, Campo G, Biscaglia S. Safety, efficacy and impact on frailty of mini-invasive radial balloon aortic valvuloplasty. *Heart.* 2021;107:874-80.

5. Attisano T, Silverio A, Stabile E, Briguori C, Tuccillo B, Scotto Di Uccio F, Di Lorenzo E, Tesorio T, Giordano A, Calabrò P, Cappelli Bigazzi M, Golino P, Scherillo M, Vigorito F, Quaranta G, Esposito G, Mauro C, Musumeci G, Tarantini G, Galasso G; BAV for Life Investigators. Safety and feasibility of balloon aortic valvuloplasty in non-TAVI centers: The "BAV for life" experience. *Catheter Cardiovasc Interv.* 2019;93:E63-70.

6. Collet JP, Thiele H, Barbato E, Barthélémy O, Bauersachs J, Bhatt DL, Dendale P, Dorobantu M, Edvardsen T, Folliguet T, Gale CP, Gilard M, Jobs A, Jüni P, Lambrinou E, Lewis BS, Mehilli J, Meliga E, Merkely B, Mueller C, Roffi M, Rutten FH, Sibbing D, Siontis GCM; ESC Scientific Document Group. 2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. *Eur Heart J.* 2021;42:1289-367.

7. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es GA, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, Mehran R, Rodés-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *Eur Heart J.* 2012;33:2403-18.

8. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, Capodanno D, Conradi L, De Bonis M, De Paulis R, Delgado V, Freemantle N, Haugaa KH, Jeppsson A, Jüni P, Pierard L, Prendergast BD, Sádaba JR, Tribouilloy C,

Wojakowski W. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *EuroIntervention.* 2022;17:e1126-96.

9. Otto CM, Mickel MC, Kennedy JW, Alderman EL, Bashore TM, Block PC, Brinker JA, Diver D, Ferguson J, Holmes DR Jr, et al. Three-year outcome after balloon aortic valvuloplasty. Insights into prognosis of valvular aortic stenosis. *Circulation.* 1994;89:642-50.

10. Saia F, Marrozzini C, Ciuca C, Guastaroba P, Taglieri N, Palmerini T, Bordoni B, Moretti C, Dall'ara G, Branzi A, Marzocchi A. Emerging indications, in-hospital and long-term outcome of balloon aortic valvuloplasty in the transcatheter aortic valve implantation era. *EuroIntervention.* 2013;8:1388-97.

11. Saia F, Marrozzini C, Ciuca C, Bordoni B, Dall'Ara G, Moretti C, Taglieri N, Palmerini T, Branzi A, Marzocchi A. Is balloon aortic valvuloplasty safe in patients with significant aortic valve regurgitation? *Catheter Cardiovasc Interv.* 2012;79:315-21.

12. Bhattacharyya S, Lloyd G. Mortality whilst waiting for intervention in symptomatic severe aortic stenosis. *Eur Heart J Qual Care Clin Outcomes.* 2020;6:89-90.

13. Elbaz-Greener G, Masih S, Fang J, Ko DT, Lauck SB, Webb JG, Nallamothu BK, Wijeysundera HC. Temporal Trends and Clinical Consequences of Wait Times for Transcatheter Aortic Valve Replacement: A Population-Based Study. *Circulation.* 2018;138:483-93.