ORIGINAL ARTICLE

Elective versus rescue balloon aortic valvuloplasty for critical aortic stenosis

Paweł Tyczyński[1], Zbigniew Chmielak[1], Maciej Dąbrowski[1], Jarosław Skowroński[1], Krzysztof Kukuła[1], Patrycjusz Stokłosa[2], Marcin Demkow[3], Miłosz Marona[4], Witold Śmigielski[5], Janina Stępińska[4], Tomasz Hryniewiecki[2], Adam Witkowski[1]

1 Department of Interventional Cardiology and Angiology, The Cardinal Stefan Wyszyński National Institute of Cardiology, Warsaw, Poland
2 Department of Acquired Heart Diseases, The Cardinal Stefan Wyszyński National Institute of Cardiology, Warsaw, Poland
3 Department of Coronary and Structural Heart Diseases, The Cardinal Stefan Wyszyński National Institute of Cardiology, Warsaw, Poland
4 Department of Intensive Cardiac Therapy, The Cardinal Stefan Wyszyński National Institute of Cardiology, Warsaw, Poland
5 Unit of Demography, University of Łódź, Łódź, Poland

KEY WORDS
balloon aortic valvuloplasty, elective intervention, rescue intervention

EDITORIAL
by Kamran et al, see p. 956

ABSTRACT

BACKGROUND Balloon aortic valvuloplasty (BAV) may be considered a bridge to further intervention in hemodynamically unstable patients or patients with symptomatic severe aortic stenosis (AS).

AIMS This study aimed to retrospectively compare periprocedural and in-hospital outcomes of AS patients treated with elective BAV (group 1) and rescue BAV (group 2).

METHODS We identified 35 patients in whom BAV was performed between 2010 and 2018. Among them, 16 were treated electively (group 1) and 19 urgently (group 2).

RESULTS Overall, BAV resulted in a significant decrease in the mean transaortic gradient by a median (interquartile range [IQR]) value of 5 (1–10) mm Hg (P <0.01) and the maximal transaortic gradient by a median (IQR) value of 13.5 (2.5–23.2) mm Hg (P <0.01). Postprocedural grade II aortic regurgitation rates increased from 8.6% to 17.1% (P = 0.48). Periprocedural death occurred in 4 patients (11.4%)—all from group 2 (21%) (P = 0.1). In-hospital death occurred in 15 patients (42.8%)—3 patients (18.7%) from group 1 and 12 patients (63.1%) from group 2 (P <0.01). During follow-up, a single patient underwent surgical aortic valve replacement, and transcatheter aortic valve implantation was performed in 4 individuals. A single patient died 22 months after BAV.

CONCLUSIONS Periprocedural and in-hospital mortality in patients with critical AS treated with BAV remains very high, especially in patients treated urgently.

INTRODUCTION Severe aortic stenosis (AS) poses an ever-growing healthcare problem. Balloon aortic valvuloplasty (BAV) was proposed in 1986 as a palliative procedure or an alternative to surgical aortic valve replacement (SAVR).[1] Soon afterwards, it was shown that only the first of these 2 indications is viable. The introduction of transcatheter aortic valve implantation (TAVI) has revived interest in this issue. The current Polish and European Society of Cardiology guidelines recommend TAVI in patients with severe symptomatic AS ineligible for SAVR owing to the prohibitive perioperative risk (European System for Cardiac Operative Risk Evaluation II [EuroSCORE II] >8%).[2] Nowadays, BAV is rarely performed as a standalone procedure. The intervention may constitute a bridge to SAVR or TAVI in hemodynamically unstable patients[3] or in symptomatic patients with AS who require urgent major noncardiac surgery. It may also serve as a diagnostic procedure in patients with AS as well as with other potential causes of symptoms and finally as an option in patients with severe end-organ dysfunction that could be reversed by BAV. Other contraindications to TAVI, which result in considering treatment with BAV, include ongoing

Correspondence to:
Paweł Tyczyński, MD, PhD, Department of Interventional Cardiology and Angiology, The Cardinal Stefan Wyszyński National Institute of Cardiology, ul. Alpejska 42, 04-628 Warszawa, Poland, phone: +48 22 343 42 72, e-mail: medykpol@wp.pl
Received: November 11, 2019.
Revision accepted: April 15, 2020.
Published online: April 17, 2020.
Kardiol Pol. 2020; 78 (10): 982-989
doi:10.33963/KP.15299

WHAT'S NEW?

To the best of our knowledge, this is the first study specifically comparing periprocedural and in-hospital mortality in 2 groups of patients: those who underwent rescue balloon aortic valvuloplasty (BAV) and those after an elective BAV procedure. We related our data to findings obtained in other studies reporting mortality in at least 1 of these patient groups. The comparison showed very high in-hospital mortality rates in post-BAV patients with aortic stenosis, particularly in the setting of rescue interventions.

infective endocarditis or a too large aortic annulus. Studies analyzing such patient subpopulations are scarce.

Cardiogenic shock and hemodynamic instability are among the most common and less disputed indications for BAV. Still, the benefits of elective BAV remain unclear.[4]

Morbidity and mortality associated with elective BAV is considerable (in-hospital mortality, 2%–15%).[5] There are very few studies directly comparing mortality in patients undergoing elective and urgent BAV. However, the urgent procedure has been associated with an approximately 6-fold higher mortality rate than that reported in elective BAV.[6]

Here, in a relatively uniform patient group from a single center, we attempted to investigate whether the excess mortality in patients undergoing urgent BAV is indeed much higher than in those undergoing the elective procedure. Perhaps, BAV should be performed more frequently in patients who are still stable and await TAVI.

The primary objective of the study was to retrospectively compare interventional and in-hospital outcomes of symptomatic AS patients treated with elective BAV (group 1) and rescue BAV (group 2). The secondary objective included follow-up assessment limited to any repeated intervention on the aortic valve performed in our institution or death.

METHODS **Patient population** We identified consecutive patients who underwent elective (group 1) or rescue BAV (group 2) between July 2010 and August 2018 in the Cardinal Stefan Wyszyński National Institute of Cardiology, Warsaw, Poland.

Elective BAV was considered a diagnostic modality in AS patients with other potential causes of symptoms and a therapeutic option in those with severe myocardial dysfunction yet hemodynamically stable, ie, with New York Heart Association (NYHA) class II, III, or ambulatory IV, renal failure, or other organ dysfunction that resulted in some contraindications to TAVI and could be reversed with BAV.

The term 'rescue BAV' was used if at least 1 major factor (pre-BAV pulmonary edema or resuscitation during the same hospitalization) or a combination of 2 minor factors (intravenous inotropic agents and intravenous loop diuretics administered during the same hospitalization before BAV) prompted BAV.

Demographic data, medical history, and clinical characteristics were prospectively collected in all study patients.

Diabetes was defined according to the 2012 American Diabetes Association diagnostic criteria (hemoglobin A_{1C} ≥6.5% or fasting plasma glucose ≥126 mg/dl, or 2-hour postload plasma glucose ≥200 mg/dl). Hypertension was defined as a systolic blood pressure higher than or equal to 140 mm Hg or a diastolic blood pressure higher than or equal to 90 mm Hg, or the self-reported use of antihypertensive drugs. Estimated glomerular filtration rate was calculated using the Modification of Diet in Renal Disease (MDRD) equation.

The study was approved by the institutional ethics committee (IK-NPIA-0021-88/1809/19). Informed consent was waived because of the retrospective study design.

Echocardiographic assessment Standard complete transthoracic echocardiography was performed in each patient before the procedure and before hospital discharge in those who survived BAV. Severe AS was diagnosed when the mean aortic gradient was higher than 40 mm Hg and / or the aortic valve area was smaller than 1 cm^2. Preintervention valvular (aortic and mitral) regurgitation was assessed according to the current echocardiographic guidelines and classified as I (mild), II (moderate), or III (significant).[7]

Balloon aortic valvuloplasty technique The technical aspects of BAV were described in detail elsewhere.[8] The choice of the balloon size was left at the operator's discretion (considering the oval shape and the smaller diameter of the annulus). Aortic balloon inflation was performed most frequently during the rapid pacing of the right ventricle, usually at the rate of 160 to 180 bpm. If aortic regurgitation was severe after BAV, TAVI was considered. If BAV was followed by hemodynamic instability or features of acute myocardial ischemia on electrocardiography, urgent coronary angiography was performed.

EuroSCORE II assessment EuroSCORE II (http://www.euroscore.org/calc.html) was calculated based on the following rules: the operation-related factor in the calculator was set as "emergency" for the rescue-BAV patients and as "elective" for the elective-BAV patients.

The BAV procedure was considered successful if a reduction of the mean transaortic gradient of 50% or greater was achieved and no moderate or severe aortic regurgitation (AR) was observed.

TABLE 1 Baseline characteristics of the study patients

Characteristic		All patients (n = 35)	Elective BAV (n = 16)	Rescue BAV (n = 19)	*P* value
Clinical variables					
Age, y, mean (SD)		77.7 (8.8)	77.9 (9)	77.5 (8.8)	0.91
Men, n (%)		21 (60)	8 (50)	13 (68.4)	0.27
Diabetes, n (%)		13 (37.1)	5 (31.2)	8 (42.1)	0.51
Dialysis, n (%)		2 (5.7)	0	2 (10.5)	0.49
Arterial hypertension, n (%)		18 (51.5)	6 (37.5)	12 (63.1)	0.13
Atrial fibrillation, n (%)		19 (54.3)	8 (50)	11 (57.9)	0.64
Previous AMI, n (%)		11 (31.4)	4 (25)	7 (36.8)	0.49
Previous stroke, n (%)		5 (14.3)	1 (6.2)	4 (21)	0.35
Previous PCI, n (%)		13 (37.1)	7 (43.7)	6 (31.6)	0.5
Previous CABG, n (%)		3 (8.6)	1 (6.2)	2 (10.5)	>0.99
Previous valve surgery, n (%)		4 (11.4)	2 (12.5)	2 (10.5)	>0.99
NYHA functional class III–IV, n (%)		31 (88.6)	12 (75)	19 (100)	0.03
EuroSCORE II, median (IQR)		24.6 (29.6)	6.3 (19.5)	30.7 (18.4)	<0.01
Laboratory data					
WBC, $\times 10^3$/µl, median (IQR)		8.6 (4.9)	6.8 (3)	9.3 (5.6)	0.24
Hemoglobin, g/dl, mean (SD)		11.3 (2.1)	11.6 (1.8)	11.1 (2.3)	0.56
Creatinine, µmol/l, mean (SD)		144.8 (74.6)	113.0 (45.2)	171.7 (84.5)	0.02
eGFR, ml/min/1.73 m^2, mean (SD)		46.4 (20.3)	55.6 (19.8)	38.6 (17.6)	0.01
hs-CRP, mg/dl, median (IQR)		1.4 (2.8)	0.6 (2.1)	1.7 (2.7)	0.1
Glucose, mmol/l, median (IQR)		6.3(2.2)	6.3 (1.3)	7 (2.3)	0.3
AST, U/l, median (IQR)		20 (19.7)	22.5 (13.2)	18.5 (71.7)	0.61
ALT, U/l, median (IQR)		17 (18.2)	18 (13.5)	14 (17)	0.41
Preoperative medication, n (%)					
Intravenous	Any inotropic agent	14 (40)	1 (6.2)	13 (68.4)	<0.01
	Epinephrine	1 (2.8)	0	1 (5.3)	>0.99
	Norepinephrine	2 (5.7)	0	2 (10.5)	0.49
	Dopamine	11 (31.4)	1 (6.2)	10 (52.6)	<0.01
	Dobutamine	7 (20)	0	7 (36.8)	<0.01
	Loop diuretic	25 (71.4)	8 (50)	17 (89.5)	0.02
Oral	ASA	25 (71.4)	12 (75)	13 (68.4)	0.72
	β-Blocker	31 (88.6)	16 (100)	15 (78.9)	0.11
	ACEI or ARB	16 (45.7)	8 (50)	8 (42.1)	0.64
	Loop diuretic	22 (62.8)	12 (75)	10 (52.6)	0.29
	Statin	21 (60)	12 (75)	9 (47.4)	0.17

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ALT, alanine transaminase; AMI, acute myocardial infarction; ARB, angiotensin receptor blocker; ASA, acetylsalicylic acid; AST, aspartate transaminase; BAV, balloon aortic valvuloplasty; CABG, coronary artery bypass grafting; eGFR, estimated glomerular filtration rate; EuroSCORE II, European System for Cardiac Operative Risk Evaluation II; hs-CRP, high-sensitivity C-reactive protein; IQR, interquartile range; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; WBC, white blood cells

TABLE 2 Procedural, pre- and postinterventional echocardiographic, and postprocedural data

		All patients (n = 35)	Elective BAV (n = 16)	Rescue BAV (n = 19)	*P* value
Procedural characteristics					
Balloon size, mm, mean (SD)		22.2 (2.3)	22.5 (2.8)	21.7 (2.3)	0.36
Preinterventional TTE measurements					
Transaortic gradient, mm Hg, mean (SD)	Mean	46.4 (19.7)	47.9 (19.1)	45.9 (20.8)	0.88
	Maximal	76.4 (28.4)	76.7 (27.9)	76.2 (29.5)	0.97
RVSP, mm Hg, mean (SD)		55 (15.3)	48 (15.4)	60.1 (13.6)	0.05
RVSP >50 mm Hg, %		66.7	50	78.6	0.2
LVEF, %, mean (SD)		34.4 (17.3)	37.8 (19.2)	31.5 (15.4)	0.29
LVEF <25%, n (%)		14 (40)	6 (37.5)	8 (42.1)	0.78
LVEDD, mm, mean (SD)		54.7 (8.5)	54.7 (8.5)	54.7 (8.7)	0.98
AVA, cm^2, mean (SD)		0.6 (0.2)	0.6 (0.1)	0.6 (0.2)	0.85
Grade II–III MR, %		25	0	5.3	>0.99
TAPSE, mm, mean (SD)		16.1 (5.2)	18.3 (5.1)	13.1 (3.9)	0.04
AR, n (%)	Grade I	31 (88.6)	14 (87.5)	17 (89.5)	>0.99
	Grade II	3 (8.6)	2 (12.5)	1 (5.3)	0.58
	Grade III	1 (2.9)	0	1 (5.6)	–
Bicuspid aortic valve, n (%)		6 (17.1)	5 (31.2)	1 (5.3)	0.07
Postinterventional TTE measurements					
Successful BAV, n (%)		1 (2.9)	1 (6.2)	0	>0.99
Transaortic gradient, mm Hg, mean (SD)	Mean	37.2 (16.4)	39.6 (16.6)	33.7 (16.3)	0.39
	Maximal	58.7 (23.8)	64.6 (22.5)	51.9 (24.2)	0.15
Decrease in the transaortic gradient, mm Hg, median (IQR)	Mean	5 (1–10)[a]	6 (0–13.5)	5 (4.25–9.25)	0.89
	Maximal	13.5 (2.5–23.2)[b]	7 (0.5 –8.5)	19 (8–26.25)	0.13
RVSP, mm Hg, mean (SD)		55.5 (5.8)	54.2 (8)	56.7 (0.6)	0.58
AR, n (%)	Grade I	28 (80)	12 (75)	16 (84.2)	0.68
	Grade II	6 (17.1)	4 (25)	2 (10.5)	0.38
	Grade III	1 (2.9)	0	1 (5.6)	>0.99
Concomitant PCI, n (%)		5 (14.3)	3 (18.7)	2 (10.5)	0.64
Post-BAV TAVI, n (%)		4 (11.4)	1 (6.2)	3 (15.8)	0.6

a *P* <0.01 for the difference between preinterventional and postinterventional mean transaortic gradients

b *P* <0.01 for the difference between preinterventional and postinterventional maximal transaortic gradients

Abbreviations: AR, aortic regurgitation; AVA, aortic valve area; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; RVSP, right ventricular systolic pressure; TAPSE, tricuspid annular plane systolic excursion; TTE, transthoracic echocardiography; others, see TABLE 1

TABLE 3 Univariate predictors of in-hospital mortality after balloon aortic valvuloplasty

Predictor	OR	95% CI	*P* value
NYHA class	19	2–185	0.01
EuroSCORE II	1.1	1–1.2	0.01
Use of intravenous diuretics before BAV	11.5	1.2–113.8	0.04
Use of intravenous inotropic agents before BAV	11.3	2.1–61.6	0.01
Combination of intravenous diuretic use / intravenous inotropic agent use / PE / resuscitation before BAV	4.7	1.7–13.2	<0.01
Maximal transaortic gradient before BAV	1	0.9–1	0.05
BAV urgency status (elective vs rescue)	15.2	2.4–95.2	<0.01

Abbreviations: OR, odds ratio; PE, pulmonary edema; others, see TABLE 1

Follow-up was limited to intraprocedural or in-hospital mortality and to any repeated aortic valve intervention (re-BAV, TAVI, or SAVR) at our center and death.

Statistical analysis Continuous variables were expressed as mean (SD) or median (interquartile range [IQR]) depending on the normality of data distribution assessed by the Shapiro–Wilk test. Categorical variables were presented as numbers and percentages.

Numerical variables were assessed with the *t* test or the Mann–Whitney test for non-normally distributed variables. Categorical data were compared using the χ^2 test or the Fisher exact test, as appropriate. A *P* value less than 0.05 was considered significant. Univariate logistic regression analysis was conducted to determine the predictors of in-hospital mortality. All statistical analyses were performed using the MedCalc software, version 9.3.8.0 (MedCalc, Ostend, Belgium).

RESULTS

Thirty-five patients were included in the study (men, 60%; mean [SD] age, 77.7 [8.8] years), out of which 16 were treated electively (group 1) and 19 urgently (group 2) with BAV (TABLE 1).

The main indication for elective BAV in group 1 patients was a diagnostic procedure to determine the reversibility of symptoms before possible TAVI or SAVR. However, half of these patients were ineligible for TAVI because of an ongoing infection (n = 3), a too large aortic annulus, a too small femoral artery (n = 4), or unfavorable take-off of the coronary arteries (n = 1).

The median (IQR) time between patient admission to an intensive care unit and the BAV procedure in group 2 was 1 (0–2) days.

Patients in group 1, compared with group 2, were characterized by a significantly better functional NYHA class (III–IV, 76% vs 100%; *P* = 0.03), had a significantly lower median (IQR) EuroSCORE II (6.3 [19.5] vs 30.7 [18.4]; *P* <0.01), lower mean (SD) creatinine levels (113 [45.2] µmol/l vs 171.7 [84.5] µmol/l; *P* = 0.02), and a higher mean (SD) estimated glomerular filtration rate (55.6 [19.8] ml/min/1.73 m^2 vs 38.6 [17.6] ml/min/1.73 m^2; *P* = 0.01).

No significant differences were found between both study groups regarding AS severity on echocardiography (TABLE 2). Right ventricular function, expressed by mean (SD) tricuspid annular plane systolic excursion, was poorer in group 2 compared with group 1 (13.1 [3.9] mm vs 18.3 [5.1] mm; *P* = 0.04).

Procedural outcomes Any postprocedural transaortic gradient measurements (intraoperative or performed during patients' stay in an intensive care unit or a discharge ward) were available in 31 patients (88.6%). Overall, BAV resulted in a significant median (IQR) decrease in the mean transaortic pressure by 5 (1–10) mm Hg (*P* <0.01) and a significant median (IQR) decrease in the maximal transaortic pressure by 13.5 (2.5–23.2) mm Hg (*P* <0.01). No significant differences in the postprocedural decrease of transaortic gradients (mean and maximal) were observed between both study groups. Procedural success was not achieved in any group (only a single patient from group 1 met the criteria for procedural success).

Postprocedural grade II AR increased from 8.6% to 17.1% (*P* = 0.48). No change in right ventricular systolic pressure was noted.

Periprocedural death (within 72 hours) occurred in 4 patients (11.4%), all from group 2 (21.8%; *P* = 0.1). Three of them died in the catheterization laboratory, and a single patient died 2 hours after the procedure.

In-hospital outcomes Overall, in-hospital death occurred in 15 patients (42.8%). Three of them (18.7%) were from group 1, and 12 (63.1%) from group 2 (*P* <0.01). The median (IQR) time from the procedure to in-hospital death was 6 (1–14) days.

Predictive parameters of in-hospital mortality Univariate logistic regression analysis revealed 7 predictors of in-hospital mortality: NYHA class,

TABLE 4 Selected recent studies (and the historic Mansfield registry) on balloon aortic valvuloplasty by an increasing number of patients

Study	Study subject	BAV urgency status	Logistic EuroSCORE, %	EuroSCORE II, %	Patients, n	In-hospital mortality, %	Follow-up mortality, %
Calicchio et al[14]	Bridge to urgent, noncardiac surgery	Urgent (rescue)	31.1	–	15	0	0
Debry et al[15]	BAV in hypotensive vs nonhypotensive CS	Urgent (rescue)	–	41.6	44	45	47 (at 1 month)
Ford et al[16]	High operative risk	Elective	25.2	–	51	0	38.9 (at 1 month)
Attisano et al[17]	BAV in non-TAVI centers	–	28.4	6.1 and 10.8[a]	55	9.1	–
Daly MJ et al[4]	High operative risk	Elective and urgent (rescue)	35.7	–	64	3	13 (at 1 month)
Dall'Ara et al[5]	Comparison of intraprocedural rapid ventricular pacing vs no pacing	Elective	–	6 and 6.1[a]	100	2	3 (at 1 month)
O'Neill[18]	The Mansfield registry of nonsurgical patients	–	–	–	492	7.5	23.8 (at 7 months)
Moretti et al[19]	A multicenter European registry	–	14.1	–	811	–	6.6 and 6.2[a] (at 1 month)
Alkhouli et al[6]	The National Inpatient Sample Registry	Elective and urgent (rescue)	–	–	3168	8.5	–

a Depending on the study subgroup

Abbreviations: CS, cardiogenic shock; others, see TABLE 1

EuroSCORE II, use of intravenous diuretics before BAV, use of intravenous inotropic agents before BAV, a combination of intravenous diuretic use / intravenous inotropic agent use / pulmonary edema / resuscitation before BAV, transaortic gradients before BAV (maximal), and the BAV urgency status (TABLE 3).

A single patient had ischemic stroke a day after BAV. Neither transient ischemic attack nor serious bleedings were observed.

The survivors (n = 20) received the following drugs at discharge: acetylsalicylic acid (65%), clopidogrel (35%), any anticoagulant (55%), angiotensin-converting enzyme inhibitor (90%), β-blocker (95%), statin (70%), and loop diuretic (100%).

Regarding the follow-up (limited to any aortic valve reintervention at our institution or death), a single patient underwent SAVR a month after BAV, and successful TAVI was performed in 4 patients (in a single patient from group 1 and 3 patients from group 2). All 5 patients survived the interventions and were discharged home.

Finally, a single patient underwent repeated BAV 14 months after the first procedure. The first BAV resulted in a decreased mean hemodynamic gradient from 81 mm Hg to 61 mm Hg. However, no such decrease was observed on echocardiography (change of the transaortic gradient from 110/62 mm Hg [maximal / mean] to 96/64 mm Hg). The second BAV resulted in a decrease in the mean hemodynamic gradient from 68 mm Hg to 34 mm Hg and a decrease in the aortic gradient on echocardiography from 119/70 mm Hg to 39/26 mm Hg. Nonetheless, the patient died 20 days later. Also, a single patient died 22 months after BAV.

DISCUSSION Here, we presented the retrospectively analyzed outcomes of a single-center cohort of patients treated with BAV for severe AS over 8 years. A comparison between rescue and elective BAV outcomes with regard to periprocedural and in-hospital mortality is a novelty. Our findings confirmed the previously reported high in-hospital mortality in AS patients after BAV procedure, especially in the setting of rescue interventions (it exceeded 60% in our study subgroup). Nonetheless, the in-hospital mortality rate of 17.6% in our elective-BAV patients is definitely not negligible and higher than rates reported in previous studies.

Thus, some questions arise (especially concerning the rescue-BAV group): 1) Is very high mortality a consequence of irreversible multiorgan failure, not depending on the BAV procedure?; 2) Is there any helpful (or harmful) role of BAV?; 3) If so, what might make it more effective (timing and technical issues)?; 4) Are there any BAV-specific predictive tools that might help answer these questions?; 5) What is the role of periprocedural mechanical support, especially in patients undergoing rescue BAV?

Comorbidities and patient selection for BAV The postprocedural mortality risk, expressed by EuroSCORE II, was extremely high in the rescue-BAV group (33.9%). Also, the elective-BAV group was characterized by high-risk features (12.7%), and the risk was higher than previously reported in cohorts of patients with AS (TABLE 4). This might partially explain our disappointing results in both patient subgroups.

Interestingly, AS severity (expressed by the baseline transaortic gradient and the aortic valve area) and systolic left ventricular function (expressed by left ventricular ejection fraction) did not significantly differ between both study groups. Indeed, the baseline intergroup difference was seen in worse renal function, increased levels of inflammatory markers (a significant increase in high-sensitivity C-reactive protein levels and a nonsignificant increase in white blood cell count), and a higher EuroSCORE II in the rescue-BAV group. Next, only high-sensitivity C-reactive protein levels and EuroSCORE II were among the predictive factors of in-hospital mortality in univariate logistic regression analysis. Since patients treated electively with BAV were at high risk, they were ineligible for TAVI. This is in line with a study by Saia et al,[9] in which less than half of TAVI candidates ineligible for surgery actually fulfilled the TAVI criteria, and a severe noncardiac comorbidity was the reason for exclusion in around half of the cases.[9]

Intervention The decision to perform or refrain from rescue BAV in unstable patients was based on our Heart Team assessment. Puri et al[10] proposed an integrated approach (with TAVI-specific scores incorporated into the current American guidelines) to identify TAVI patients at very high risk, in whom futile postprocedural outcomes could be expected. Of note, the prohibitive risk score from any intervention suggested that there was a 30-day mortality risk exceeding 25% (as assessed by the TAVI-specific score). Moreover, a combined risk of irreversible morbidity or mortality at 30 days higher than 50% (based on a somehow enigmatic assessment by a cardiologist and 2 cardiac surgeons) was considered operatively prohibitive in an expert consensus of the American cardiac societies.[11]

Efficacy of balloon aortic valvuloplasty Postprocedural decrease in the mean transaortic gradient above 50% was observed only in a single study patient, and no difference was noted for the whole cohort. A trend toward a decrease in the maximal transaortic gradient was seen. This is in contrast with observations in a much healthier (EuroSCORE II, 6%; left ventricular ejection fraction >50%) Italian cohort of 100 patients, in which a 50% reduction in the mean trans-valvular gradient on echocardiography was reported in as many as 42.9% and 39.2% (depending on the subgroups) of patients after BAV.[5] Furthermore, it remains unclear whether a failure in transaortic gradient reduction in our study cohort would explain high in-hospital mortality. Lack of significant transaortic gradient reduction has been associated with a much worse survival at long-term follow-up.[12]

In the majority of our study patients, we only used a single short (around 5-second) balloon inflation with the balloon diameter calculated according to the shorter native aortic annulus diameter measured by multislice computed tomography or echocardiography, regardless of the immediate post-BAV transaortic gradient. Dall'Ara et al[5] presented a different protocol, which consisted of a sequence of at least 3 balloon inflations.[5] Most authors just overlooked this technical issue. Some of them report 2 to 3 inflations. Nonetheless, multiple short balloon inflations might be considered an alternative; however, with the caveat of a potentially increased rate of stroke.

Mortality prediction scores Our post-hoc stratification of the BAV-related risk of in-hospital mortality was based on EuroSCORE II. This model and the Society of Thoracic Surgeons score are most widely used algorithms to stratify the mortality risk associated with TAVI or BAV. Nonetheless, as observed in patients undergoing cardiac surgery, these scores have inherent limitations, which were discussed in detail elsewhere.[13] No BAV-specific risk score has been established so far. However, 3 TAVI risk scores have been developed: PARTNER TAVI, TVT, and FRANCE 2 TAVI scores. Still, a low-to-moderate discriminatory power of these models remains a limitation for a proper identification of TAVI patients at high risk.

Limitations Due to a retrospective design of the study, some of the previously reported pre- and postinterventional parameters (such as bicuspid aortic valve, frailty, porcelain aorta, chest wall radiation, chest wall deformity, body mass index / body surface area, quality of life scale, or activity of life scores) were not included in the patient risk assessment. Thus, only EuroSCORE II was used in this study to assess BAV-related mortality. For the same reason, no data on possible postprocedural complications, such as stroke, need for permanent pacing, access site complications, serious bleeding, or blood transfusion, were presented.

The definition of the BAV urgency status (elective or rescue) used in this study and based on major and minor factors was at the discretion of the study authors. Thus, the selection bias of these criteria was inevitable.

Patients with AS and cardiogenic shock who did not undergo rescue BAV were not included in our database and, thus, no comparison between such patient groups was performed.

A relatively small number of patients precluded multivariate logistic regression analysis for the identification of independent risk factors of in-hospital mortality.

Clinical follow-up data were not available for all discharged patients and, therefore, were not included in the study.

Conclusions Periprocedural and in-hospital mortality of patients treated with BAV for critical AS remains very high, especially in urgent settings.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

HOW TO CITE Tyczyński P, Chmielak Z, Dąbrowski M, et al. Elective versus rescue balloon aortic valvuloplasty for critical aortic stenosis. Kardiol Pol. 2020; 78: 982-989. doi:10.33963/KP.15299

REFERENCES

1 Cribier A, Savin T, Saoudi N, et al. Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: an alternative to valve replacement? Lancet. 1986; 1: 63-67.

2 Parma R, Zembala MO, Dąbrowski M, et al. Transcatheter aortic valve implantation. Expert consensus of the Association of Cardiovascular Interventions of the Polish Cardiac Society and the Polish Society of Cardio-Thoracic Surgeons, approved by the Board of the Polish Cardiac Society and National Consultants in Cardiology and Cardiac Surgery. Kardiol Pol. 2017; 75: 937-964.

3 Saia F, Marrozzini C, Ciuca C, et al. Emerging indications, in-hospital and long-term outcome of balloon aortic valvuloplasty in the transcatheter aortic valve implantation era. EuroIntervention. 2013; 8: 1388-1397.

4 Daly MJ, Monaghan M, Hamilton A, et al. Short-term efficacy of palliative balloon aortic valvuloplasty in selected patients with high operative risk. J Invasive Cardiol. 2012; 24: 58-62.

5 Dall'Ara G, Marzocchi A, Taglieri N, et al. Randomized comparison of balloon aortic valvuloplasty performed with or without rapid cardiac pacing: the pacing versus no pacing (PNP) study. J Interv Cardiol. 2018; 31: 51-59.

6 Alkhouli M, Zack CJ, Sarraf M, et al. Morbidity and mortality associated with balloon aortic valvuloplasty: a national perspective. Circ Cardiovasc Interv. 2017; 10. pii: e004481.

7 Lipiec P, Bąk J, Braksator W, Fijałkowski M, et al. Transthoracic echocardiography in adults – guidelines of the Working Group on Echocardiography of the Polish Cardiac Society. Kardiol Pol. 2018; 76: 488-493.

8 Ooms JFW, van Wiechen M, Ziviello F, et al. Tools and techniques: single access balloon aortic valvuloplasty – an overview of contemporary technical improvements. EuroIntervention. 2019. pii: EIJ-D-19-00074.

9 Saia F, Marrozzini C, Dall'Ara G, et al. How many patients with severe symptomatic aortic stenosis excluded for cardiac surgery are eligible for transcatheter heart valve implantation? J Cardiovasc Med (Hagerstown). 2010; 11: 727-732.

10 Puri R, Iung B, Cohen DJ, Rodés-Cabau J. TAVI or no TAVI: identifying patients unlikely to benefit from transcatheter aortic valve implantation. Eur Heart J. 2016; 37: 2217-2225.

11 Holmes DR Jr, Mack MJ, Kaul S, et al. 2012 ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement: developed in collaboration with the American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Mended Hearts, Society of Cardiovascular Anesthesiologists, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. Ann Thorac Surg. 2012; 93: 1340-1395.

12 Kamperidis V, Hadjimiltiades S, Ziakas A, et al. Balloon valvuloplasty as destination therapy in elderly with severe aortic stenosis: a cardiac catheterization study. J Geriatr Cardiol. 2015; 12: 218-225.

13 O'Sullivan CJ, Stortecky S, Buellesfeld L, et al. Preinterventional screening of the TAVI patient: how to choose the suitable patient and the best procedure. Clin Res Cardiol. 2014; 103: 259-274.

14 Calicchio F, Guarracino F, Giannini C, et al. Balloon aortic valvuloplasty before noncardiac surgery in severe aortic stenosis: a single-center experience. J Cardiovasc Med (Hagerstown). 2017; 18: 109-113.

15 Debry N, Kone P, Vincent F, et al. Urgent balloon aortic valvuloplasty in patients with cardiogenic shock related to severe aortic stenosis: time matters. EuroIntervention. 2018; 14: e519-e525.

16 Ford TJ, Nguyen K, Brassil J, et al. Balloon Aortic valvuloplasty in the transcatheter valve era: single centre indications and early safety data in a high risk population. Heart Lung Circ. 2018; 27: 595-600.

17 Attisano T, Silverio A, Stabile E, et al. Safety and feasibility of balloon aortic valvuloplasty in non-TAVI centers: the "BAV for life" experience. Catheter Cardiovasc Interv. 2019; 93: E63-E70.

18 O'Neill WW. Predictors of long-term survival after percutaneous aortic valvuloplasty: report of the Mansfield Scientific Balloon Aortic Valvuloplasty Registry. J Am Coll Cardiol. 1991; 17: 193-198.

19 Moretti C, Chandran S, Vervueren PL, et al. Outcomes of patients undergoing balloon aortic valvuloplasty in the TAVI era: a multicenter registry. J Invasive Cardiol. 2015; 27: 547-553.