

ORIGINAL ARTICLE

BALLOON AORTIC VALVULOPLASTY WITH VALVER BALLOON CATHETER IN ADULTS WITH SEVERE AORTIC STENOSIS AS A BRIDGE OR PALLIATIVE TREATMENT

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ABSTRACT

The aim: We aimed to assess the feasibility and safety of performing balloon aortic valvuloplasty (BAV) with Valver balloon catheter (Balton, Poland) in adults with severe aortic stenosis as a bridge or palliative treatment.

Materials and methods: We identified consecutive patients who underwent BAV procedures between May 2019 and March 2020 using Valver balloon catheters. Demographic data, medical history, and clinical characteristics were retrospectively collected in all study patients together with periprocedural data as well as 12-month follow-up data.

Results: We included 18 patients. The mean population age was 78.1 ± 8.9 years, and women were 61.1%. The most common co-morbidities were arterial hypertension (88.9%), dyslipidemia (83.3%), and coronary artery disease (72.2%). The baseline mean aortic valve pressure gradient was 49.94 ± 27.02 mmHg and the mean aortic valve area (AVA) was 0.65 ± 0.20 cm². In all cases, the procedure was performed from the femoral access via the 8F sheath. Two Valver balloon catheter sizes were used 18x40mm (33.3%) and 20x40mm (66.7%). Three periprocedural complications were observed, and none was associated with the Valver balloon catheter per se. The transthoracic echocardiography after the procedure revealed a decrease in the mean pressure gradient of 11.1 ± 8.85 mmHg, and an increase in AVA of 0.21 ± 0.19 cm². At 12-month follow-up, the mortality rate was 38.9%.

Conclusions: BAV is a procedure increasingly performed in catheterization laboratories worldwide. This paper confirmed the relative safety of BAV with Valver balloon catheters in the modern era, showing a low incidence of valve and vascular complications.

KEY WORDS: aortic stenosis; BAV; TAVI; TAVR; aortic valve area

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INTRODUCTION

Cribier et al. first described balloon aortic valvuloplasty (BAV) as an alternative therapy for selected subjects with severe calcified aortic stenosis (AS) [1]. The incipient jubilation was hurriedly hampered by BAV limited durability and inability to improve survival. Therefore, for more than 20 years, BAV was restricted only for inoperable subjects, and this treatment option was applied in palliative cases [2]. Nonetheless, the advent of transcatheter aortic valve replacement (TAVR) revived the interest in BAV as a diagnostic technique in subjects with other potential symptom causes (e.g., advanced lung disease) or as a bridge to aortic valve replacement in subjects presenting with acute decompensated AS and having substantial contraindications to TAVR [3-5].

THE AIM

Our study aimed to retrospectively assess the feasibility and safety of performing BAV with Valver balloon catheter (Balton, Poland) in adults with severe AS as a bridge or palliative treatment.

MATERIALS AND METHODS**PATIENT POPULATION**

We enrolled consecutive patients who underwent BAV procedure between May 2019 and March 2020 in the Department of Invasive Cardiology, Centre of Postgraduate Medical Education (Warsaw, Poland) using Valver balloon catheter.

BAV was a diagnostic option in AS subjects with other potential symptom causes and a therapeutic option in subjects with advanced heart muscle dysfunction, chronic kidney disease, or other organ dysfunction that posed contraindications to TAVR and might be, at least partially, reversed by BAV.

We gathered demographic data, clinical characteristics, and periprocedural data in all study subjects.

STUDY ENDPOINTS AND DEFINITIONS

The primary study endpoint was the rate of periprocedural complications with the use of the Valver balloon catheter. The secondary study endpoints included: a

change in AS echocardiographic parameters as well as the rate of myocardial infarction, stroke, and death at 3, 6, and 12 months.

Diabetes was defined according to the 2021 Diabetes Poland diagnostic criteria (hemoglobin A_{1c} ≥ 6.5% or fasting plasma glucose ≥ 126 mg/dL, or 2-hour post-load plasma glucose ≥ 200 mg/dL). Hypertension was defined as systolic blood pressure higher than or equal to 140 mm Hg or diastolic blood pressure higher than or equal to 90 mm Hg, or the self-reported use of antihypertensive drugs [6]. The estimated glomerular filtration rate was calculated using the Modification of Diet in Renal Disease (MDRD) equation. Coronary artery disease was defined based on ischemic symptoms and clinical guidelines [7, 8].

Informed consent and the institutional ethics committee were waived because of the retrospective study design.

ECHOCARDIOGRAPHIC ASSESSMENT

Each subject underwent full transthoracic echocardiography before BAV as well as before hospital discharge. Severe AS diagnostic criteria were: the mean aortic gradient > 40 mmHg and/or the aortic valve area was < 1 cm². Coexisting valvular regurgitation (aortic, mitral, and tricuspid) was analyzed according to the current echocardiographic guidelines and classified as mild (I), moderate (II), or significant (III) [9].

BALLOON AORTIC VALVULOPLASTY TECHNIQUE

All procedures were performed with Valver balloon catheter. Valver balloon catheters are semi-compliant and manufactured from organic polymers from the polyamide family. Valver balloon catheter has a double lumen body with a balloon fixed in the distal part. The external lumen is used for filling and emptying the balloon. The internal catheter's lumen enables the passage of a guidewire, which allows for directing the catheter. Two X-ray proof markers are helpful in proper positioning the balloon during the procedure. Valver balloon catheter is available in the following size ranges: 5 – 35 mm (nominal diameter) and 20 – 60 (nominal length).

The procedure was performed from the femoral access (8F sheath) under local anesthesia. The balloon diameter choice was left at the operator's discretion; however, its nominal diameter did not exceed 90% – 100% of the aortic annulus diameter measured in transthoracic echocardiography. Routinely, we performed two balloon inflations with a manual syringe. Aortic balloon inflation was performed most frequently during the rapid pacing of the right ventricle, usually at 140 to 160 bpm (Fig. 1). The puncture site was closed with a double-AngioSeal (St. Jude Medical, St. Paul, MN) technique (6F).

QCA ANALYSIS

To assess the real expansion of the balloon catheter, we performed the post-procedure analysis using CAAS QCA version 8.0 (Pie Medical, the Netherlands). The catheter's

calibration was done in each analysis. We calculated the balloon catheter diameter inflated with the recommended saline volume. The measurement was performed at the level of the aortic annulus. The measurement was performed twice, and the mean value was calculated.

STATISTICAL ANALYSIS

Continuous variables were shown as mean (SD) or median (interquartile range [IQR]) depending on the normality of data distribution assessed by the Shapiro–Wilk test. Categorical variables were expressed as numbers and percentages. Numerical variables were assessed with the t-test or the Mann–Whitney test for non-normally distributed variables. The time-to-event data were analyzed using the Kaplan–Meier estimator of the survival curve. P-value < 0.05 was judged as significant. Statistical analyses were performed using R 3.0.2 for OS (R Foundation, Vienna, Austria) [10].

RESULTS

POPULATION CHARACTERISTICS

Between May 2019 and March 2020, 18 patients underwent BAV with the use of Valver balloon catheter. The mean population age was 78.1 ± 8.9 years, and women were 61.1%. The most common co-morbidities were arterial hypertension (88.9%), dyslipidemia (83.3%), coronary artery disease (72.2%), atrial fibrillation/flutter (55.6%), diabetes (44.4%), and chronic kidney disease (44.4%). Detailed information is presented in Table 1. At admission, dyspnea (100%) and NYHA III-IV (72.2%) were most observed.

Ten patients (55.5%) received intravenous inotropic agents (dopamine – 6; dobutamine – 2; norepinephrine – 2), and 12 patients (66.7%) received intravenous loop diuretics.

AORTIC STENOSIS CHARACTERISTICS

Detailed baseline echocardiographic parameters are presented in Table 2. The mean left ventricular ejection fraction was 54.37 ± 11.18%. In 66.7% of patients, hemodynamically significant mitral regurgitation was observed, in 50% – tricuspid regurgitation, and 22.2% – aortic regurgitation.

Mean aortic valve pressure gradient (PG) was 49.94 ± 27.02 mmHg, and mean AVA was 0.65 ± 0.20 cm². Normal-flow high-gradient AS (AVA ≤ 1 cm², mean PG ≥ 40 mmHg, EF ≥ 50%) was observed in 13 patients (72.2%), low-flow low-gradient AS (AVA ≤ 1 cm², mean PG < 40 mmHg, EF < 50%) was observed in 4 patients (22.2%), and paradoxical low-flow low-gradient AS (AVA ≤ 1 cm², mean PG < 40 mmHg, EF ≥ 50%) was revealed in one patient (5.6%).

PROCEDURE CHARACTERISTICS

Procedure details are provided in Table 3. In 15 patients, the procedure was performed as a bridge therapy to TAVR/surgical

Table 1. Baseline characteristics.

Parameter	Number (%) N = 18
age	78.1 ± 8.9
women	11 (61.1)
arterial hypertension	16 (88.9)
coronary artery disease	13 (72.2)
diabetes mellitus	8 (44.4)
dyslipidemia	15 (83.3)
prior coronary artery bypass graft	1 (5.6)
prior myocardial infarction	3 (16.7)
chronic kidney disease	8 (44.4)
eGFR [mL/min/1,73m ²]	50.65 ± 21.66
cancer	4 (22.2)
atrial fibrillation/flutter	10 (55.6)
Clinical presentation	
angina pectoris	12 (66.7)
dyspnea	18 (100)
syncope	3 (16.7)
NYHA III-IV	13 (72.2)
cardiogenic shock	1 (5.6)
asymptomatic	0

eGFR – estimated glomerular filtration rate; NYHA – New York Heart Association

Table 2. Baseline echocardiographic characteristics

Parameter	Value
LVEDd [mm]	46.23 ± 5.76
IVSd [mm]	14.06 ± 2.15
PWd [mm]	12.39 ± 2.06
TAPSE [mm]	20.94 ± 5.66
EF [%]	54.37 ± 11.18
Aortic regurgitation II/III	4 (22.2)
Mitral regurgitation II/III	12 (66.7)
Tricuspid regurgitation II/III	9 (50)
Aortic valve stenosis	
peak PG [mmHg]	79.61 ± 19.21
mean PG [mmHg]	49.94 ± 27.02
Vmax [m/s]	4.40 ± 0.73
AVA [cm ²]	0.65 ± 0.20

LVEDd – left ventricular end-diastolic diameter; IVSd – intraventricular septum diameter; PWd – posterior wall diameter; TAPSE – tricuspid annular plane systolic excursion; EF – ejection fraction; PG – pressure gradient; AVA – aortic valve area

aortic valve replacement (SAVR) and in 3 patients – as a palliative option. In all cases, the procedure was performed from the femoral access via the 8F sheath. Two Valver balloon catheter sizes were used 18x40mm (33.3%) and 20x40mm (66.7%). In all cases, Valver balloon catheters reached their nominal diameters in QCA analysis (a theoretical mean

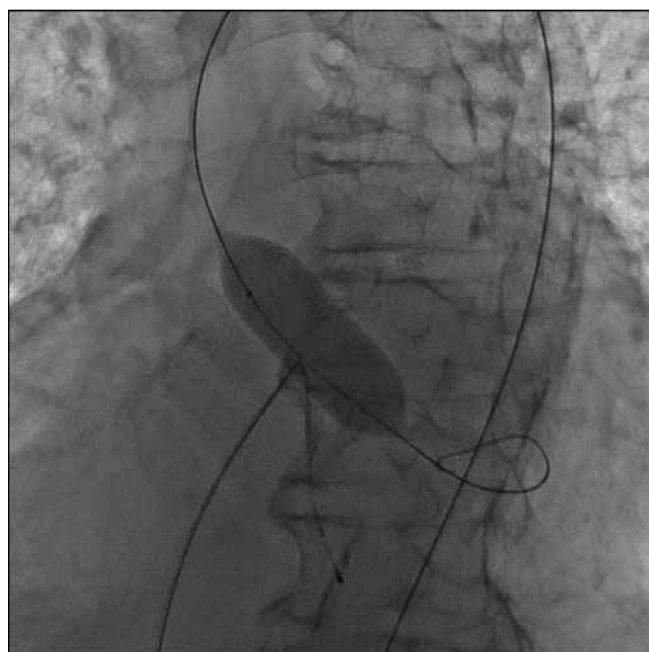


Fig. 1. The example procedure of balloon aortic valvuloplasty using Valver balloon catheter (Balton, Poland).

Table 3. Periprocedural details

Parameter	Number (%)
Indications	
Bridge to TAVR/SAVR	15 (83.3)
Palliative	3 (16.7)
Procedure	
Femoral access	18 (100)
Vascular sheath 8F	18 (100)
Valver 20x40mm	12 (66.7)
Valver 18x40mm	6 (33.3)
Pacing frequency (1/min)	150 ± 24
Balloon volume (mL)	19.83 ± 0.95
Complications	
Death*	1 (11.1)
Permanent pacemaker implantation	0
Sepsis	0
TIA/stroke	0
acute myocardial infarction	0
Access site complication types	
hematoma	0
pseudoaneurysm	2 (11.1)
thrombosis/peripheral embolization	0
arterial-venous fistula	0
nerve injury	0

*n = 1 left ventricle perforation with a guidewire, and cardiac tamponade
TAVR – transcatheter aortic valve replacement; SAVR – surgical aortic valve replacement; TIA – transient ischemic attack

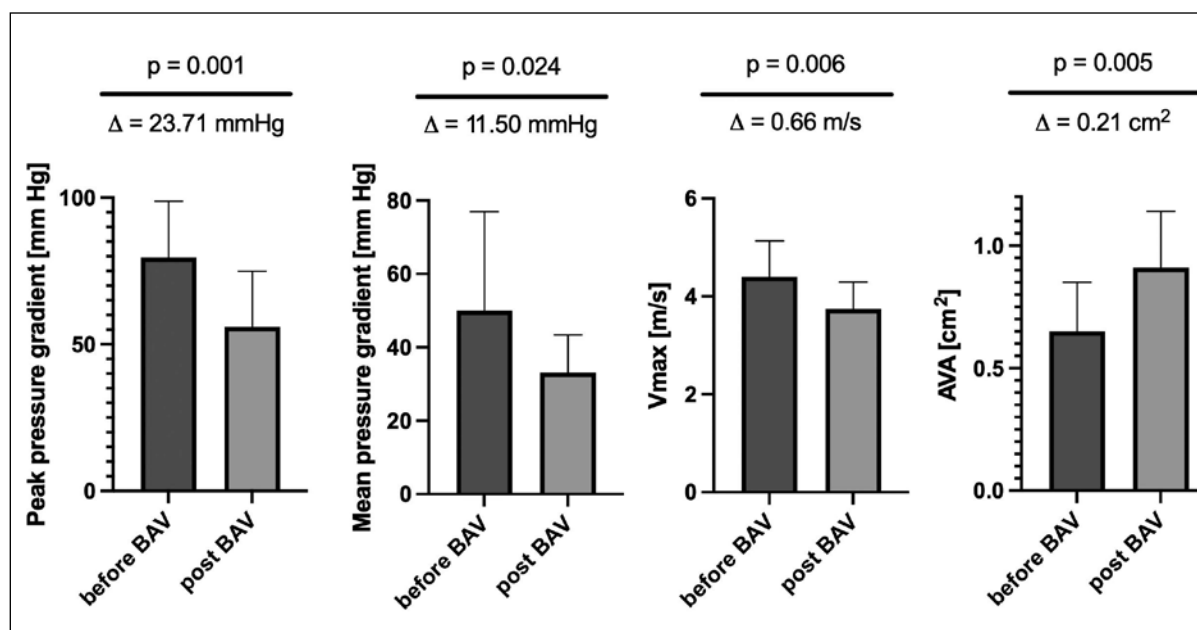


Fig. 2. Change in echocardiographic parameters before and after aortic balloon valvuloplasty. BAV – balloon aortic valvuloplasty; AVA – aortic valve area

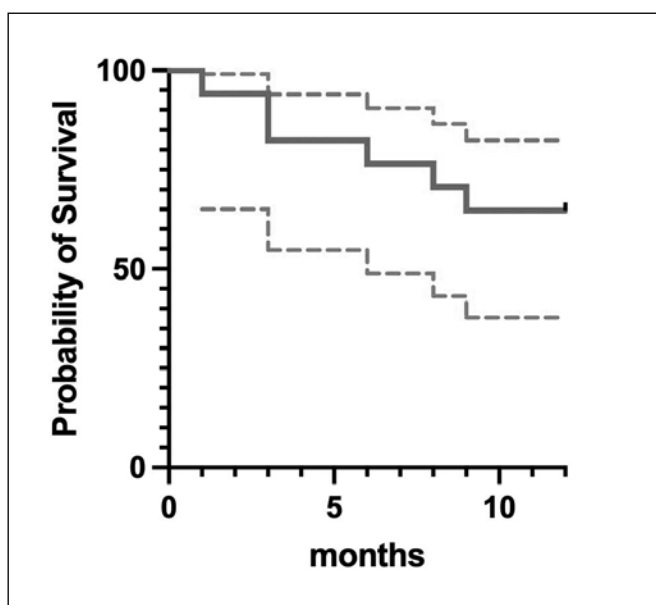


Fig. 3. All-cause mortality in patients undergoing balloon aortic valvuloplasty. A Kaplan-Meier curve with a 95% confidence interval.

nominal diameter: 19.33 ± 0.96 mm, QCA mean nominal diameter: 19.61 ± 1.13 mm).

Three periprocedural complications were observed, and none was associated with the Valver balloon catheter per se. The first complication was associated with perforation of the left ventricle with a guidewire that ended in cardiac tamponade and death ($n = 1$). The other two complications were associated with access site complications, i.e., pseudoaneurysm requiring surgical intervention and blood transfusion ($n = 2$).

The transthoracic echocardiography after the procedure revealed a decrease in peak PG by 23.71 ± 15.94 mmHg, mean PG – by 11.5 ± 8.85 mmHg, and in V_{max} – by 0.66 ± 0.48 m/s. Simultaneously, AVA increased by 0.21 ± 0.19 cm² (Fig. 2).

FOLLOW-UP

At a 3-month follow-up, two patients underwent TAVR, and one patient underwent the SAVR procedure. Also, four deaths were registered (1 – periprocedural and three due to heart failure deterioration). No myocardial infarction (MI)/transient ischemic attack (TIA)/stroke were observed.

At 12 months, 7 (38.9%) deaths were registered (1 – periprocedural, three due to heart failure deterioration, 2 – sudden cardiac death, and 1 – due to massive stroke). Also, one case of MI and one case of stroke were registered (Fig. 3).

DISCUSSION

Our study showed that the BAV procedure with Valver balloon catheters is a feasible and safe option. The device-related adverse event rate was 5.6%, and the improvement in echocardiographic aortic stenosis parameters was statistically significant and satisfactory.

The position of BAV in contemporary interventional cardiology is a subject of ongoing debates. BAV supporters state that the procedure is a beneficial temporizing option in hemodynamically compromised subjects with severe AS who are not candidates for immediate TAVR. It might also be a successful treatment option as a bridge to TAVR. Moreover, BAV is cheaper than TAVR. Therefore, BAV presents an excellent triaging/diagnostic modality in hemodynamically compromised subjects or subjects with multicausal symptoms with disputable benefit from valve replacement. Contrarians of widespread BAV use stress that BAV is linked with increased risk of stroke, severe acute aortic regurgitation, vascular adverse events, and death, distinctively bearing in mind the progress in TAVR techniques and outcomes. The latter argument is underpinned by several papers revealing that immediate TAVR in hemodynamically compromised subjects was safe and efficient, as well as might have decreased the risk of two sequential procedures [11, 12].

Our population had three palliative cases, and 15 patients were treated with BAV as a bridge therapy. There were two cases before urgent non-cardiac surgery, and in 10 cases, there were patients admitted with decompensated heart failure and who, despite several attempts, could not be discharged. Ferre et al. showed that preoperative BAV might have increased the survival rate in hip fracture subjects despite the elongation of time to the surgery. And this improved outcome might be associated with decreased rates of cardiologic and neurologic complications [13]. Regarding decompensated AS subjects, Ali et al. revealed that urgent or emergency TAVR procedures correlated with decreased mortality when compared to a strategy using BAV as a bridge to TAVR/SAVR [14]. However, the TAVR option is not always available as soon as it would be needed.

Usually, the postprocedural echocardiography discloses an increase in AVA (0.2–0.4 cm²) correlating with a 30% – 60% (approx. 15 mmHg) decrease in mean pressure gradient. We also observed a reduction of left and right ventricular filling pressures and increased cardiac output [15–18]. Certain interventional cardiologists opt for an aggressive approach (i.e., a larger balloon and higher number of dilatations) to obtain more substantial gradient reduction and moderate AS (AVA ≥ 1 cm², indexed AVA ≥ 0.6 cm²/m²) to improve survival; however, no conclusive data confirms the superiority of this treatment strategy [12, 19]. In the PNP study, operators could halve the mean pressure gradient in 35% of subjects with three inflations and in 35% of the remaining who proceeded with three more dilatations after changing to a larger balloon [20]. However, the PARTNER B trial showed no benefits in decreasing pressure gradient above 50% compared to below 50% [21]. In consequence, the hemodynamic aim of the BAV procedure should be individualized. In subjects with bridging to TAVR/SAVR, a moderate pressure gradient decrease may be enough. On the contrary, in palliative subjects postponing clinical deterioration may requisite greater gradient reduction.

In our study, due to significant aortic valve calcification, we aimed to improve hemodynamic status. The mean pressure gradient decreased by 11.5 ± 8.85 mmHg and AVA increased by 0.21 ± 0.19 cm². Thanks to this approach, we managed to discharge safely all but one patient with decompensated heart failure.

A report from U.S. BAV procedures (n = 2,127) performed between 1998 and 2010 showed an abrupt increase in the BAV number and a substantial decrease (23%) in in-hospital mortality over time [22]. The following factors might be the intending explanations: growing operator skills, increased experience in closing large-bore vascular access sites, as well as using low-profile balloon catheters. The report originating from two high-volume centers with almost 1,000 BAV procedures revealed a relatively low vascular complication rate, i.e., major complications rate – 2.7% major complications [23]. In our study, severe periprocedural complications were also relatively low. One complication associated with perforation of the left ventricle with a guidewire led to cardiac tamponade and death. After this incident, we changed the guidewire on the preshaped Safari² guidewire (Boston Scientific, Marlborough, MA). Additionally, we identified two access site complications

(within the series of the first five procedures), i.e., pseudoaneurysms requiring surgical intervention. This rate was similar to other studies assessing BAV procedures from transfemoral access [16, 17, 24].

Worth stressing is the fact that we performed all procedures with 8F sheath femoral access. This relatively small sheath size enabled us to close the puncture site with the double-AngioSeal techniques. No severe bleeding episodes were registered, but two pseudoaneurysms requiring surgical intervention were required. In the literature, some other minimalistic techniques are described. Di Cesare et al. described the case series of the BAV procedure from the snuffbox approach with an 8F sheath [25]. Also, Medina et al. showed that transradial BAV was safe, feasible (8 – 10F sheaths), and efficacious with a low conversion rate and radial artery occlusion [26]. And other authors showed that using a single Angio-Seal 8F to close transfemoral access exceeding 8F was safe [27].

Finally, in our study population mortality rate at 12 months was 38.9%. This value, although relatively high, is quite typical for this patient's population, as shown in other studies [2, 11, 15, 16, 28]. Unfortunately, only two patients underwent TAVR, and one patient underwent SAVR. This was associated with the COVID-19 pandemic and our hospital's conversion into the hospital dedicated to fighting with COVID-19 [29, 30].

Our study has several limitations. The first one is its retrospective character which is associated with its own limitations. The second one is the small sample size. However, it was enough to show the feasibility and safety of Valver balloon catheters. And, finally, the inability to further monitor and treat these patients what could compromise the results.

CONCLUSIONS

BAV is a procedure increasingly performed in catheterization laboratories worldwide. This paper confirms the relative safety of BAV with Valver balloon catheters in the modern era, showing a low incidence of valve and vascular complications.

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Conflict of interest:

Robert J Gil is a Balton company consultant.

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A – Work concept and design, **B** – Data collection and analysis, **C** – Responsibility for statistical analysis,
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