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ORIGINAL RESEARCH

Balloon Aortic Valvuloplasty – Remaining Indications in the Modern TAVR Era

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ABSTRACT

Objectives: A retrospective observational cohort study to report on contemporary indications of balloon aortic valvuloplasty (BAV).

Background: As indications for transcatheter aortic valve replacement (TAVR) are increasing, BAV is reinforced as a bridging therapy.

Methods: A total of 47 consecutive patients who underwent BAV in parallel to an existing TAVR program was retrospectively assessed for BAV indications and clinical events during 1 year of follow-up.

Results: The following indications were distinguished: bridge to destination aortic valve replacement therapy (BTD), bridge to urgent non-cardiac therapy (BTN) or palliation. BAV was performed in 20 (43%) patients as BTD, in 18 (38%) as BTN and in 9 (19%) as palliative treatment. Patients in the BTN cohort were younger (age 74.1 ± 8.3% vs. 80.7 ± 8.3% years in BTD, $p = 0.02$) with lower STS-scores (2.2% [IQR 1.3–4.6] vs. 13.0% [IQR 7.6–22.2] $p < 0.001$). Overall baseline mean transaortic gradient was 43.2 mmHg and reduced by a mean of 16.0 ± 10.1 mmHg after BAV ($p < 0.001$). Procedural mortality was 8.5% (n = 4). All-cause mortality at 30 days and 1 year was 20% and 45% in BTD, 6% and 39% in BTN and 44% and 67% in the palliative group. Aortic valve replacement (AVR) was performed in 55% of the BTD and 50% of the BTN group at 1 year. Reasons for not undergoing definite AVR were clinical deterioration in BTD and terminal comorbidity in BTN. Compared to a contemporary TAVR cohort, procedural and 1 year mortality was significantly increased in the BAV cohort.

Conclusion: BAV remains a valuable option in well-defined patient phenotypes to determine AVR feasibility, bridge to urgent non-cardiac therapy, and at times, palliation. These phenotypes represent vulnerable patients with overall poor clinical outcome.

Introduction

When first performed by Alain Cribier in 1986, Balloon Aortic Valvuloplasty (BAV) was proposed as a treatment for patients with severe aortic valve stenosis (AS) who could not undergo surgical aortic valve replacement (SAVR).[1] Initial reports confirmed transient mechanical and functional improvement that lasted out to 1 year.[2-5] Given only short-term clinical benefit, BAV as a definitive solution for degenerative AS was largely abandoned but remained an option for palliation or bridge to SAVR.[6,7]

In the pre-TAVR era, the Euro Heart Survey demonstrated that up to one-third of severe symptomatic AS patients did not undergo SAVR, illustrating a potential unmet clinical need.[8] Transcatheter aortic valve replacement (TAVR) revolutionized AS treatment and introduced a valid treatment option for patients who were deemed at prohibitive or elevated operative risk.[9–11] Concomitantly, BAV was reinforced as a bridging therapy and the number of BAV procedures increased again.[12–15] Contemporary reports confirmed transient improvement in quality of life (QoL) post BAV, but no long-term survival benefits.[7,16] The 2017 ESC/EACTS guidelines for the management of valvular heart disease suggest BAV may be considered as a bridge to surgery or TAVR, or a diagnostic tool.[17] Various studies positioned BAV as a bridge to destination therapy (SAVR or TAVR), bridge to decision, bridge to diagnosis, palliation or preceding urgent non-cardiac therapy[12,16-24,17,21,25] (Supplementary Table 1).

Herein we report our recent BAV experience and aim to define patient phenotypes that might warrant a temporary treatment effect of BAV.

Materials and methods

We retrospectively collected 47 consecutive AS patients who underwent BAV in the Erasmus University Medical Center between September 2012 and November 2018. Patients with congenital, non-calcified, aortic stenosis were excluded. A multidisciplinary heart team involving imaging specialists, interventional cardiologists, cardiac surgeons, and geriatricians evaluated the clinical setting, comorbidities, frailty status, and multi-modality imaging, including echocardiography

and multi-slice-computed tomography (MSCT), to determine the indication for BAV by consensus. The rationale for BAV was explicitly mentioned and included BAV as a bridge to definite aortic valve replacement (BTD), BAV as a bridge to urgent non-cardiac therapy (BTN) or palliation. By using BAV as a diagnostic tool, one would assess for TAVR futility. Therefore, this indication was incorporated in the BTD group. The palliative patients were considered moribund or to have a limited life expectancy precluding SAVR or TAVR due to severely impaired LVEF or hemodynamic instability combined with excessive frailty and (multi-) organ failure.

Patient demographics, comorbidities, frailty status, Society of Thoracic Surgeons (STS) predicted risk of mortality, transthoracic echocardiography parameters and procedural data including invasive hemodynamics were collected in a dedicated database. Aortic regurgitation was graded according to the latest guidelines.[26] All patients were followed up in the outpatient clinic at 30 days and 1-year post-BAV. Clinical endpoints were classified according to the most recent VARC-2 criteria.[27] Additionally, baseline STS-score, NYHA class as well as (post-) procedural mortality rate were compared between the BAV and corresponding TAVR cohort.

Written informed consent for the BAV procedure and subsequent data analysis for research purposes was provided by every patient. The study was conducted in accordance with the principles of the Declaration of Helsinki and did not fall under the scope of the Medical Research Involving Human Subjects Act per EMC Institutional Review Board.

Throughout the study period, BAV execution was refined into the current single-access standard.[28] The procedure typically evolves under local anesthesia (excluding all sedation). Common femoral artery access is obtained with ultrasound guidance and a 12 to 14 F sheath is inserted. The aortic valve is crossed with an 0.035 straight tipped guidewire through a 6 F AL-1 or AL-2 diagnostic catheter. After crossing, the diagnostic catheter is exchanged for a 7 F dual lumen pigtail shaped Langston catheter (Vascular Solutions, Minneapolis, MN, USA) that allows simultaneous pressure measurement in the left ventricle and the ascending aorta. The invasive hemodynamic assessment includes determination of the transvalvular pressure gradient and the aortic regurgitation (AR) index, in which the diastolic pressure difference between aorta and LV is expressed as a fraction of the systolic blood pressure. An AR index of >25% makes an aortic regurgitation of > moderate unlikely.[29] A pre-shaped 0.035" Safari guidewire (Boston Scientific, Marlborough, MA, USA) is then introduced through the Langston catheter that is then exchanged for a valvuloplasty balloon. Balloon sizing typically relies on the minimum diameter of the elliptical aortic valve annulus as determined by MSCT or on the left ventricular outflow tract diameter as measured by transthoracic echocardiography. Left ventricular pacing at 180 bpm is performed by connecting the temporary pacemaker with cable clips to the Safari wire and a subcutaneous needle at the level of the femoral access site and therefore precludes venous access.

After balloon valvuloplasty, invasive hemodynamics are reassessed with the dual lumen Langston catheter. The peak gradient is defined as the instantaneous transaortic gradient.

A multi-modality assessment of aortic regurgitation includes contrast aortography, transthoracic echocardiography, and AR index calculation.

The procedure ends with percutaneous arteriotomy closure using either suture or plug-based closure devices. The procedure goal was an adequate gradient reduction and improvement of clinical condition without causing or worsening aortic regurgitation. A 20% mean transaortic gradient reduction was deemed clinically relevant with no increase of AR to >moderate.

Statistics

Continuous variables are presented as mean ± standard deviation (SD) if normally distributed. Median with interquartile range [IQR] is provided if not normally distributed. Mean differences for normally distributed independent continuous data were analyzed using unpaired t tests. For pre- and post-procedural differences in normally distributed continuous variables a paired t test was used. Mann–Whitney U test was used if not normally distributed. Nominal data are presented as frequencies and compared using either Pearson's Chi-square or Fisher's exact test for unpaired data, McNemar's test for paired data. The association between the use of BAV or TAVR with mortality at 30-days and 1-year follow-up was investigated with Cox regression models. Models were adjusted for baseline STS-score and year of procedure. Results were reported as hazard ratios. A two-sided p value of <0.05 was considered to indicate statistical significance.

Results

The study population consisted of 47 BAV patients treated between 2012 and 2018. Mean age was 78.0 (±8.6) years, median STS-PROM was 7.3% [IQR 3.5–15.6] and the majority of patients were in NYHA class III or IV. The rationale for BAV was BTD in 20 patients (42.6%), BTN in 18 patients (38.3%) and palliative therapy in 9 patients (19.1%). Baseline demographics stratified for treatment rationale are tabulated in Table 1. Compared to BTD, BTN patients were younger (age 74.1 ± 8.3 vs. 80.7 ± 8.3 years, $p = 0.02$) and had a significantly lower STS-PROM (2.2% [1.3–4.6] vs. 13.0% [7.6–22.2] $p < 0.001$). All patients in the palliative cohort had a do-not-resuscitate status (DNR). Reason for BTD BAV was acute heart failure in 12 patients (60%), cardiogenic shock in 3 patients (15%), acute coronary syndrome in 2 patients (10%), current poor condition due to transient cardiac illness in 2 patients (10%) and arterial vascular disease in one patient (5%).

In the BTN cohort, one patient required emergent vascular surgery to treat an ulcerating foot, one required treatment for severe hepatic cirrhosis, one required urgent biliary surgery and the other 15 patients (83%) faced an oncologic problem in the process of staging or requiring surgery. All palliative patients were not considered candidates for future valve replacement due to poor hemodynamic condition combined with excessive frailty and (multi-) organ failure.

Table 1. Baseline patient characteristics by balloon aortic valvuloplasty indication. Continuous values are presented as mean ± SD and tested by Student's t-test or as median with [interquartile range] and tested by Mann–Whitney rank sum test. Categorical data is presented as frequencies with (proportions) and tested by the Chi-square test.

	Bridge to destination therapy group (BTD) (n = 20)	Bridge to urgent non-cardiac therapy group (BTN) (n = 18)	p-Value	Palliative (n = 9)
Age, years	80.7 ± 8.3	74.1 ± 8.3	0.02	79.7 ± 7.7
Male	11 (55.0)	14 (77.8)	0.18	6 (66.7)
STS-PROM score, %	13.0 [7.6–22.2]	2.2 [1.3–4.6]	<0.001	6.1 [5.1–27.3]
NYHA functional class				
I	0	3 (16.7)	0.001	0
II	2 (10.0)	7 (38.9)		1 (11.1)
III	7 (35.0)	8 (44.4)		4 (44.4)
IV	11 (55.0)	0		4 (44.4)
DNR status	4 (20.0)	0	0.11	9 (100.0)
Hypertension	15 (75.0)	11 (61.1)	0.49	1 (11.1)
Diabetes Mellitus	9 (45.0)	5 (27.8)	0.33	2 (22.2)
Elevated Creatinine	8 (40.0)	2 (11.1)	0.07	3 (33.3)
Liver disease	1 (5.0)	1 (5.6)	1.00	1 (11.1)
CVD	6 (30.0)	1 (5.6)	0.09	2 (22.2)
PVD	9 (45.0)	6 (33.3)	0.52	4 (44.4)
COPD	6 (30.0)	4 (22.2)	0.72	1 (11.1)
Malignancy[a]	1 (5.0)	15 (83.3)	<0.001	2 (22.2)
Atrial fibrillation	8 (40.0)	4 (22.2)	0.31	2 (22.2)
CAD	14 (70.0)	11 (61.1)	0.73	6 (66.7)
LVEF, %	45.0 [30.0–50.0]	52.5 [37.3–55.0]	0.10	40.0 [27.5–55.0]
Previous MI	11 (55.0)	5 (27.8)	0.11	3 (33.3)
Previous CABG	5 (25.0)	4 (22.2)	1.00	1 (11.1)
Previous PCI	8 (40.0)	4 (22.2)	0.31	2 (22.2)
Previous valve surgery	0	0	-	0
Permanent Pacemaker	3 (15.0)	3 (16.7)	1.00	1 (11.1)

Notes. [a]Proven or suspected malignancy. BAV, balloon aortic valvuloplasty; BTD, bridge to destination therapy; BTN, bridge to urgent non-cardiac therapy; CABG, coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; DNR, do not resuscitate status; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease; STS-PROM, Society of Thoracic Surgeons Predicted Risk of Mortality.

Procedural characteristics and invasive hemodynamic data of the overall population are summarized in Table 2. The mean transaortic gradient dropped by 16.0 ± 10.1 mmHg ($p < 0.001$), mean proportional gradient reduction was 37.2 ± 17.6%. Peak gradient reduction was 19.5 ± 13.4 mmHg ($p < 0.001$). The AR index measured pre- and post-BAV did not change. Overall procedural success was achieved in 78.7% of the patients. Reasons for no success were either peri-procedural death or not achieving more than 20% mean transaortic gradient reduction. One patient experienced an increase of aortic regurgitation to >moderate. Two patients in the palliation cohort experienced electromechanical dissociation after BAV and died. One patient, in the BTD group, died of electromechanical dissociation and one died of respiratory failure, both within 24 h after BAV. This resulted in an overall procedural mortality of 8.5%. Procedural success in BTD, BTN, and Palliation group was 85%, 77.8%, and 66.7%, respectively.

Follow-up data of all patients was available at 30 days. Three patients (6.4%) did not complete 1-year follow-up. Overall all-cause mortality was 19.1% (n = 9) and 46.8% (n = 22) at 30 days and 1 year, respectively (Table 3). Overall de novo pacemaker rate at 30 days was 6.4% (n = 3). Thirty-day and 1-year all-cause mortality were 20.0% and 45% vs. 5.6% and 38.9% vs. 44.4% and 66.7% in the BTD, BTN, and palliative cohort, respectively.

Cause of death at 30 days was cardiac in 75.0% for BTD, none for BTN and 100% for the palliative cohort and 66.7%, 28.6% and 100% at 1 year, respectively.

At 30 days, the NYHA class was improved in 40% (15 of 31) of patients ($p = 0.017$). Improvement at 1 year was not statistically significant. In none of the patients was a re-BAV performed during follow-up. Fifty five percent (n = 11) of BTD proceeded to definite aortic valve replacement (AVR) vs. 50% (n = 9) in BTN. Of these, one patient underwent SAVR, the remainder TAVR. The median time to definite AVR in the BTD group was 97 days (IQR: 41–146), in the BTN group 173 days (IQR: 143–233).

In the BTN group, 12 patients (66.7%) received non-cardiac therapy with a median time to urgent non-cardiac therapy of 32 days (IQR: 18–56) after BAV. Six (33%) patients turned out to have advanced oncologic disease with poor prognosis and proceeded with palliative treatment without oncologic surgery or AVR (Figure 1). After 1 year of follow up, eight patients had undergone TAVR and one SAVR.

Nine patients (45%) in the BTD group did not undergo definitive valve replacement therapy after BAV. Reasons were: severe progressive renal dysfunction (n = 4), palliation due to excessive frailty with no clinical improvement after BAV (n = 4), and procedural death (n = 1). Of these patients, who advanced to a palliative setting, 7 (78%) had died within

Table 2. Hemodynamic improvement after balloon aortic valvuloplasty.

	Pre-BAV (n = 47)	Post-BAV (n = 47)	Change	p-Value
Peak gradient, mm Hg	54.2 ± 20.5	33.2 ± 14.9	−19.5 ± 13.4	<0.001
Mean gradient, mm Hg	43.2 ± 14.9	25.9 ± 9.8	−16.0 ± 10.1	<0.001
AR-index	0.33 ± 0.1	0.34 ± 0.1	0.01 ± 0.09	0.53
AVA, cm^{2a}	0.68 ± 0.2	0.86 ± 0.3	0.19 ± 0.2	0.003
AR grade^a			-	-
None	32 (68.1)	25 (56.8)		
Mild	10 (21.3)	14 (31.8)		
Moderate	5 (10.6)	4 (8.5)		
Severe	-	1 (2.1)		
AR, moderate to severe^a	5 (10.6)	5 (10.6)	-	1.00
MR, moderate to severe^a	12 (25.5)	10 (21.3)	-	0.69

Notes. Continuous values are presented as mean ± SD and tested by the (paired) Student's t-test. Categorical data is presented as frequencies with (proportions) and tested by the Chi-square test if non-paired or McNemar's test if paired. Peak and mean gradient over the aortic valve were obtained using invasive transvalvular pressure measurements. The AR-index was calculated by dividing the invasively measured diastolic pressure difference between the aorta and left ventricle by the systolic blood pressure.
^{a}Measured using transthoracic echocardiography, in the post-BAV group, 3 patients did not have echocardiographic data available.
AVA, aortic valve area; AR, aortic regurgitation; AVA, aortic valve area; AR, aortic regurgitation; MR, mitral regurgitation.

1 year. Conversely, of the patients who were successfully bridged to AVR, two (18%), died within 1 year.

In the same timeframe that the BAV cohort was treated, a total of 832 patients underwent TAVR (Table 4). Mean age was 78.9 (±7.9) years, median STS-PROM was 4.4% [IQR 2.9–6.7] and the majority of patients were in NYHA class III or IV. Compared to the TAVR cohort, the baseline STS was significantly higher in the BAV cohort (7.3% [3.5–15.6] vs. 4.4% [2.9–6.7], p = 0.002). Additionally, procedural mortality was significantly increased in the BAV group (8.5% vs. 4.7%, p = 0.008). No differences in 30-day mortality were observed. Compared to TAVR, BAV was associated with excess mortality at 1-year follow-up (BAV: hazard ratio [HR]: 3.1; 95% confidence interval [CI]: 1.9 to 5.2; p < 0.001) (Figure 2). Analysis with imputed results for missing data showed similar results.

Discussion

This retrospective observational study identifies three phenotypes of patients that are eligible for BAV in the current era of AS management: BAV as a bridge to definite aortic valve replacement (BTD), BAV as a bridge to urgent non-cardiac therapy (BTN) or BAV as palliative treatment. BAV proved valuable to provide a transient improvement in symptoms, identify futility and bridge to (semi-) urgent non-cardiac therapy.

The rationale for BAV was BTD in 20 patients (42.6%), BTN in 18 patients (38.3%) and palliative therapy in 9 patients (19.1%). The relative portion of BTD reflects earlier work (Supplementary Table 1). However, we reported a smaller palliation cohort. This could be the result of adding a specific phenotype of patients with (non-staged) malignancy that requires further diagnostics or non-cardiac therapy. In former reports, these patients might have been counted in a palliative or a bridge to decision category. Furthermore, expanding indications for TAVR and accepting patients with increasingly extensive comorbidities might have resulted in a lower proportion of patients with a palliative indication. Indeed, the median STS-score in our BTD cohort was higher than of bridged groups in previous reports.[20,21] BTN patients were younger, less symptomatic with fewer co-morbidities and a lower STS-PROM. Severe AS was often an incidental finding in the BTN cohort yet precluded major non-cardiac surgery. BAV was therefore necessary and effective in order to proceed with this non-cardiac therapy.

Procedural success was 78.7% based on at least a 20% transvalvular gradient reduction with an increase of AR to >moderate in one patient. This is less than in previous reports where procedural success was described as >50% reduction of mean gradient.[16] However, the majority of BAVs performed in our cohort were those to bridge to either TAVR or non-cardiac treatment. The BAV goal was a temporary transaortic gradient reduction and concomitant improvement of the clinical condition in order to bridge patients to a more durable therapy, while not causing or aggravating aortic regurgitation. Prior BAV data suggested that clinical improvement could be

Table 3. Clinical outcomes at 30 Days and 1 Year according to balloon aortic valvuloplasty indication.

	30 Days			1 Year^a		
	BTD (n = 20)	BTN (n = 18)	Pall (n = 9)	BTD (n = 20)	BTN (n = 18)	Pall (n = 9)
Death	4 (20.0)	1 (5.6)	4 (44.4)	9 (45.0)	7 (38.9)	6 (66.7)
Cardiac Death	3 (15.0)	0.0	4 (44.4)	6 (30.0)	2 (11.1)	6 (66.7)
Cardiac Death as % of deaths within group	75.0	0.0	100.0	66.7	28.6	100.0
Stroke	1 (5.0)	0.0	0.0	1 (5.0)	1 (5.6)	0.0
Major vascular complication	1 (5.0)	0.0	1 (11.1)	2 (10.0)	1 (5.6)	1 (11.1)
Major bleeding	2 (10.0)	0.0	1 (11.1)	3 (15.0)	1 (5.6)	1 (11.1)
AKI	4 (20.0)	0.0	2 (22.2)	6 (30.0)	1 (5.6)	2 (22.2)
Pacemaker de novo	2 (10.0)	1 (5.6)	0.0	3 (15.0)	2 (11.1)	0.0
MI	0.0	0.0	0.0	1 (5.0)	1 (5.6)	0.0
NYHA Improvement	8 (40.0)	5 (27.8)	2 (22.2)	4 (20.0)	2 (11.6)	1 (11.1)
Final valve replacement	-	-	-	11 (55.0)	9 (50.0)	0.0

Notes. Categorical data is presented as frequencies with (proportions). ^{a}Cumulative numbers. NYHA improvement: increase of ≥1 class compared to baseline.
AKI, acute kidney injury; BTD, bridge to definite aortic valve replacement; BTN, bridge to non-cardiac therapy; MI, myocardial infarction; NYHA, New York Heart Association; Pall, palliative.
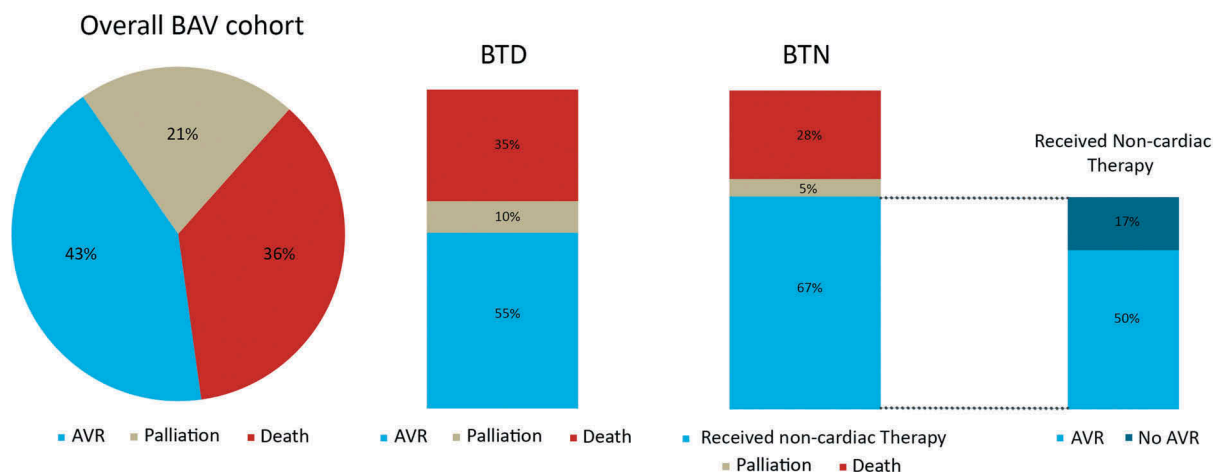
Figure 1. Successive events in overall, BTD and BTN group 1 year post balloon aortic valvuloplasty of the total BAV cohort, successive events were as follows: AVR (*n* = 20), Palliation (*n* = 10), Death (*n* = 17). BTD group: AVR (*n* = 11), Palliation (*n* = 2), Death (*n* = 7). BTD group: Received non-cardiac therapy (*n* = 12), Palliation (*n* = 1), Death (*n* = 5). Of the patients receiving non-cardiac therapy, nine had undergone AVR at 1 year (50% of total BTN group) and 3 had not (17% of total BTN group). Patients were censored for mortality if AVR preceded and vice versa. AVR, Aortic Valve Replacement; BTD, Bridge to definitive aortic valve replacement; BTN, Bridge to non-cardiac therapy.

Table 4. Balloon aortic valvuloplasty versus transcatheter aortic valve replacement versus in a corresponding timeframe.

	BAV (n = 47)	TAVI (n = 832)	Hazard Ratio[a] (95% CI)	p-Value
Baseline				
Age, years	78.0 ± 8.6	78.9 ± 7.9	-	0.34
STS-PROM, %	7.3 [3.5–15.6]	4.4 [2.9–6.7]	-	0.002
NYHA class			-	<0.001
I	3/47 (6.4)	38/806 (4.7)		
II	10/47 (21.3)	244/806 (30.3)		
III	19/47 (40.4)	433/806 (53.7)		
IV	15/47 (31.9)	91/806 (11.3)		
Procedural				
Procedural mortality	4/47 (8.5)	12/832 (1.4)	-	0.008
Follow-up				
30 day mortality	9/47 (19.1)	36/747 (4.8)	2.1(0.8–5.2)	0.13
1 year mortality	22/47 (46.8)	101/747 (13.5)	3.1 (1.9–5.2)	<0.001

Notes. All TAVR- and BAV-procedures performed in the Erasmus University Medical Center from September 2012 to November 2018. Continuous values are presented as mean ± SD and tested by the Student's t-test or as median with [interquartile range] and tested by Mann–Whitney rank sum test. Categorical data is presented as frequencies with (proportions) and tested by the Chi-square test.
[a]Compared using a Cox regression model. CI denotes confidence interval.
TAVR, Transcatheter Aortic Valve Replacement; BAV, Balloon Aortic Valvuloplasty; NYHA, New York Heart Association; STS-PROM, Society of Thoracic Surgeons Predicted Risk Of Mortality.

expected after an increase of only 0.1–0.2 cm.[22] Kapadia et al. suggested that even a modest increase in AVA could lead to a significant short-term increase of functional status and QoL.[7] Contemporary BAV reports still report new pacemaker necessity, stroke, severe aortic regurgitation, and cardiac death as the main complications after BAV.[7,16,18] These complications may be partly associated with structural damage during inflation with larger balloons. By deliberate balloon undersizing, we aimed to achieve therapeutic benefit while reducing the complication rate. In our population, AR-index remained stable and the overall 30-day de novo pacemaker rate was 6.4% (n = 3). Overall procedural mortality was relatively high

and NYHA class improved only partially, which in our opinion attests to the palliative setting of treated patients and confirms the value of BAV in the current era of AS management to avoid futility for TAVR or SAVR. In aggregate, these findings support our practice to use relatively undersized balloons for BAV and settle with at times modest (e.g. >20%) gradient reductions.

The mortality rate in the BTD group after BAV was 20.0% and 45.0% at 30 days and 1 year, respectively. This rate is higher than in previous reports.[7,21] In the PARTNER B cohort, 30-day mortality of the medical treatment group, of which 57% received a first BAV, was 2.8% which is low compared to our BTD cohort. An explanation for this difference can be the relatively poor baseline status of BTD patients with higher STS-scores (14.7% vs. 12.0%), greater renal impairment (40.0% vs. 8.8% with creatinine of >2 mg/dl) and poor LV-function (45.0% [IQR: 30.0–50.0]).[7] However, the goal of bridging to definitive valve replacement therapy implies that the condition at the moment of BAV is uncertain to benefit from any kind of valve replacement therapy. BTD is, therefore, a tool to assess whether AVR is beneficial at a later moment in time. In our study, 55% of BTD patients proceeded with AVR with a median of 97 days (IQR: 41–146). In the other 45%, poor condition persisted and justified transition to a palliative setting. Overall, the 1-year mortality in the BTD cohort remained high. In this BTD cohort, patients who were no longer eligible for AVR had a 77% 1-year mortality as compared to 18% in the patients who did undergo AVR.

Given the short-lived hemodynamic and symptomatic benefits of BAV, its use as a palliative treatment for severe AS is established.[7,12,13,22] Patients in the palliative cohort were at high risk for procedural events and faced a grim 1-year prognosis. The relatively small size of the palliation cohort is in line with the observation of shifting boundaries of TAVR eligibility. The remaining patients are the most frail and vulnerable with no further treatment options.

One year cumulative survival after BAV or TAVI
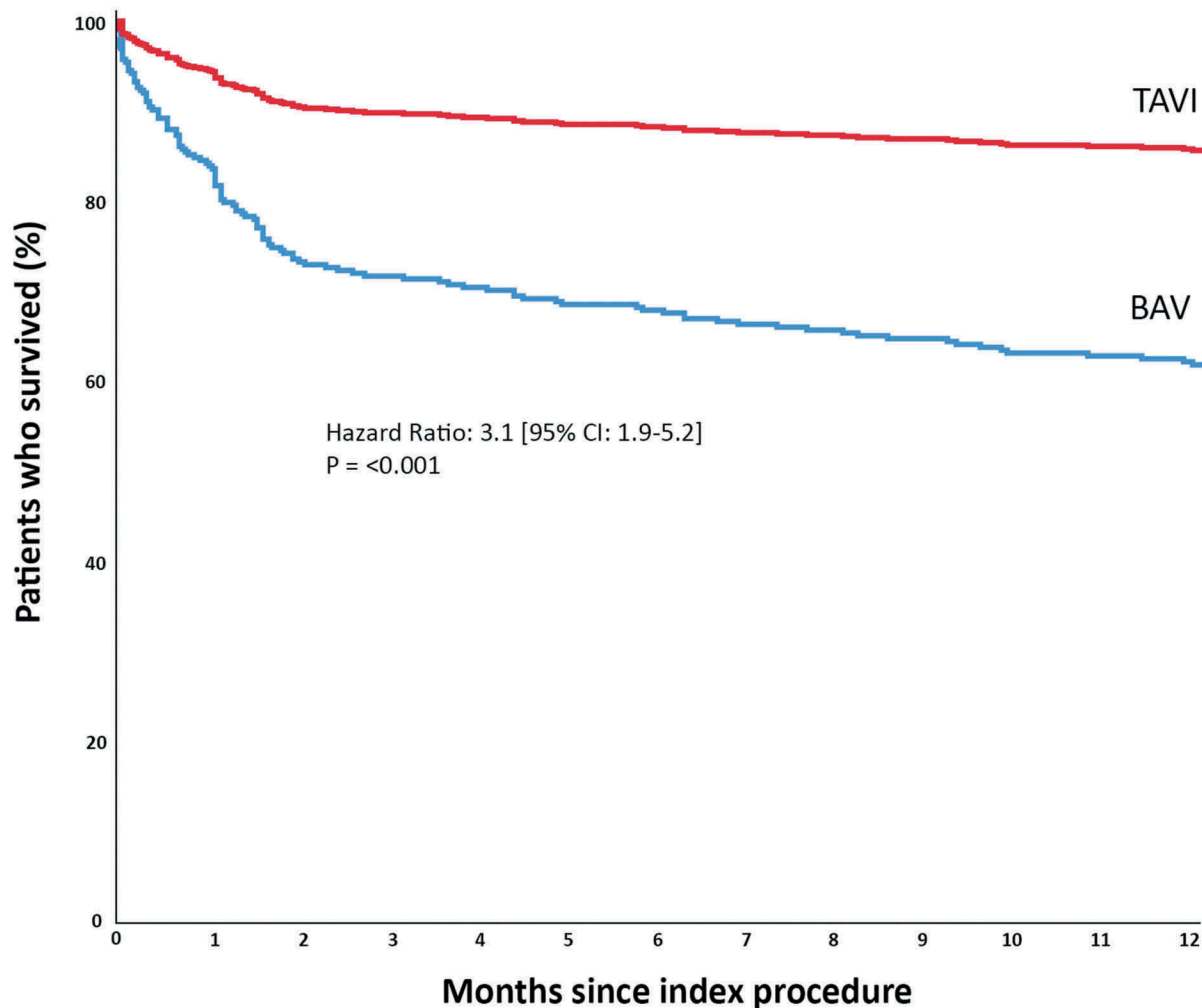
Figure 2. One year cumulative survival after BAV or TAVR. Depicted are the cumulative survival curves after index BAV or TAVR over a 1-year period. A total of 22/47 deaths occurred in the BAV group versus 101/747 in the TAVR group. BAV, balloon aortic valvuloplasty; CI, confidence interval; TAVR, transcatheter aortic valve replacement.

In comparison to the EMC TAVR cohort, BAV patients had different baseline characteristics and higher mortality at 1 year. BAV patients had more comorbidities that can explain this higher event rate. A recent propensity-matched analysis already suggested acceptable outcome with a BAV strategy versus TAVR.[15]

The BAV patient profile represents a continuum that extends into futility. The challenge for contemporary heart teams is to identify the patients who would benefit from TAVR, who would need a BAV to bridge or as palliative therapy and in whom BAV is no longer feasible because of an unacceptable procedural risk for major complications. Clearly, there is a continued need for more refined risk stratification to avoid unacceptably high BAV procedure risk and respect clinical realism. Indeed, the three in-hospital deaths were patients with end-stage heart failure with no prospect of improvement in symptoms. Although easily performed, BAV might in some cases be a bridge too far.

Our study defines an AS patient phenotype, BTN, characterized by younger age, fewer cardiac morbidities and oncologic disease that might particularly benefit from BAV. These patients may require (semi-) urgent non-cardiac surgery that might determine the overall life expectancy. A "therapy deadlock" may result from the fact that severe AS could be a contraindication for major non-cardiac surgery and, on the flipside, high-grade malignancy might limit life-expectancy and preclude AVR. BAV might offer a transient improvement in AS to allow for non-cardiac surgery without the risk of AVR futility.[30,31]

The acceptable procedural BAV complication rate and swift execution of non-cardiac therapy (median 32 days, IQR 18–56), prove the viability of BAV as a bridging modality in this particular clinical setting. We reported a 38.9% 1-year mortality in the BTN cohort, driven by non-cardiac causes, which underscores the impact of the underlying comorbidity. Of patients in the BTN group who proceeded with non-cardiac therapy, 75% eventually had definite aortic valve replacement at 1 year.

This retrospective observational study has several inherent limitations. First, our cohort is relatively small and reflects practice in one single institution. Second, our BAVs were performed over a 6 year-timespan in which our BAV technique gradually converted into a single-access procedure introducing dual lumen catheters for simultaneous pressure measurement, LV guidewire mediated pacing and dedicated large-bore vascular closure devices.

This may have resulted in procedural differences between patients. The effect of single-access BAV in terms of patient eligibility and procedure safety needs further research.

Conclusion

Balloon aortic valvuloplasty remains a valuable option in well-defined phenotypes of patients to determine AVR feasibility, bridge to (semi-) urgent non-cardiac therapy and at times, palliation. These phenotypes represent vulnerable patients with overall poor clinical outcome.

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Disclosure statement

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