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Balloon aortic valvuloplasty as a bridge-to-decision in high risk patients with aortic stenosis: a new paradigm for the heart team decision making

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Abstract

Background Whilst the majority of the patients with severe aortic stenosis can be directly addressed to surgical aortic valve replacement (AVR) or transcatheter aortic valve implantation (TAVI), in some instances additional information may be needed to complete the diagnostic workout. We evaluated the role of balloon aortic valvuloplasty (BAV) as a bridge-to-decision (BTD) in selected high-risk patients. **Methods** Between 2007 and 2012, the heart team in our Institution required BTD BAV in 202 patients. Very low left ventricular ejection fraction, mitral regurgitation grade ≥ 3 , frailty, hemodynamic instability, serious comorbidity, or a combination of these factors were the main drivers for this strategy. We evaluated how BAV influenced the final treatment strategy in the whole patient group and in each specific subgroup. **Results** Mean logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) was $23.5\% \pm 15.3\%$, age 81 ± 7 years. In-hospital mortality was 4.5%, cerebrovascular accident 1% and overall vascular complications 4% (0.5% major; 3.5% minor). Of the 193 patients with BTD BAV who survived and received a second heart team evaluation, 72.6% were finally deemed eligible for definitive treatment (25.4% for AVR; 47.2% for TAVI); 96.7% of patients with left ventricular ejection fraction recovery; 70.5% of patients with mitral regurgitation reduction; 75.7% of patients who underwent BAV in clinical hemodynamic instability; 69.2% of frail patients and 68% of patients who presented serious comorbidities. **Conclusions** Balloon aortic valvuloplasty can be considered as bridge-to-decision in high-risk patients with severe aortic stenosis who cannot be immediate candidates for definitive transcatheter or surgical treatment.

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1 Introduction

A sizable proportion of patients with severe aortic stenosis (AS) have clinical conditions that may preclude definitive treatment with surgical aortic valve replacement (AVR) or transcatheter aortic valve implantation (TAVI).^[1–3] Advanced age, left ventricular dysfunction, or associated comorbidities represent the major reasons for denying cardiac surgery.^[4] TAVI provides treatment for high or prohibitive surgical risk patients with symptomatic severe AS who either were previously not referred for or were denied cardiac surgery.^[5–7] However, many patients may present temporary

or definitive contraindications for TAVI including, among others, clinical instability, very low ejection fraction, associated severe valve disease, pulmonary hypertension, severe comorbidity and frailty. In addition, a sizable group of patients die or lack improvement in quality of life or functional status soon after TAVI raising important questions about futility in some patients.^[8–10] Although to a lesser degree, futility may come into question also for some extreme-risk AVR procedures.^[11]

A multidisciplinary heart valve team, including different areas of expertise, may better evaluate a number of factors in addition to traditional risk stratification in an attempt to anticipate the benefit of TAVI and AVR. Yet, this may remain very difficult in some instances. In this setting, percutaneous balloon aortic valvuloplasty (BAV) may provide additional and potentially useful insights. In fact, although after BAV restenosis occurs almost invariably in a few months, relevant reduction of symptoms, amelioration of

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global clinical status and improvement of echocardiographic parameters are generally observed shortly after the procedure. With the possible exception of haemodynamically unstable patients or symptomatic patients who require urgent major non-cardiac surgery, current guidelines do not support the use of BAV as a bridge to AVR or TAVI.^[12,13] Of interest, a possible role for BAV and subsequent clinical re-evaluation has been proposed in selected patients with severe AS and clinical conditions generating uncertainty within the heart team, but there are virtually no data supporting such a strategy.^[14]

With the present study we sought to evaluate the role of BAV as a “bridge-to-decision” in selected patients with severe AS and potentially reversible contraindications to definitive surgical or transcatheter treatment.

2 Methods

2.1 Patient population

All consecutive patients who underwent BAV at our institution were entered in a prospective registry. Indications to BAV, always discussed within the heart team, were the following: (1) destination therapy, i.e. palliation of symptoms in patients without other therapeutic options; (2) bridge-to-TAVI, in selected patients who have been already addressed to TAVI, with the aim of improving clinical conditions before the procedure; (3) bridge-to-AVR, in selected patients who are candidates for AVR in order to improve clinical status or reduce surgical risk; and (4) bridge-to-decision (BTD) BAV, when there was either severe clinical instability or initial heart team evaluation was not conclusive and required further clinical or instrumental evaluation. The present study focused on this last patient group. It should be highlighted that the heart team decision relies on multiple parameters, which could not be always clearly categorized. This is consistent with the recommendations of the principal cardiology and cardiac surgery societies stating that the risk assessment should mostly rely on the clinical judgment, in addition to the combination of scores and single instrumental parameters.^[12,13] For a descriptive purpose, based on the main reason for postponing final decision-making, our patients were further (and retrospectively) divided into five main subgroups of interest: (1) low left ventricular ejection fraction (LVEF < 30%); (2) mitral valve regurgitation (MVR) grade ≥ 3 ; (3) frailty,^[15] i.e., patients with a Rockwood Frailty Index = 3 or frailty index = 2 associated with at least another severe comorbidity between chronic obstructive pulmonary disease (COPD), severe renal failure (glomerular filtration rate, GFR < 30 mL/min per 1.73 m²), body mass index (BMI) < 20 or > 30 kg/m², se-

rum albumin < 3.5 g/dL and liver cirrhosis; (4) hemodynamic instability, either cardiogenic shock or acute pulmonary edema or New York Heart Association (NYHA) class IV; and (5) serious comorbidity, representing a potentially reversible contraindication for definitive treatment *per se* or in combination with other risk factors (including pulmonary hypertension, multiple comorbidities, need for urgent non cardiac surgery). Some patients presented a combination of the characteristics listed above and were included in more subgroups.

2.2 Study objectives and definitions

All patients had ambulatory visit and echocardiography scheduled one month after BTD BAV. The main objective of the study was to evaluate how BAV influenced the final heart team decision-making in the whole BTD group and in its single specific subgroups. All echocardiograms were performed at our Institution by experienced operators (years of experience 5–38). In patients with LVEF < 30%, a significant improvement was considered as an improvement > 5% or a final LVEF > 30% in conjunction with a subjective clinical benefit recorded during follow-up outpatient clinic visit; in patients with MVR grade ≥ 3 , significant improvement was defined by a final MVR < 3 using standard definitions.^[16] Importantly, final therapeutic decision formulated by the heart team did not rely only on these changes but took into account the whole patient status and life expectancy. Hence, for example, a patient with significant recovery of left ventricular ejection fraction could still be denied a definitive treatment based on a comprehensive clinical judgment. Based on this second evaluation, patients were candidates for TAVI, AVR or medical treatment (MT) with possible repeated palliative BAV (MT/BAV).

Symptomatic status was classified based on the presence of syncope, stable angina, acute coronary syndrome, dyspnea (NYHA class) or cardiogenic shock. Coronary artery disease included previous percutaneous coronary intervention, previous coronary artery bypass graft, or documented stenosis $\geq 70\%$ of a major coronary vessel by visual estimate at angiography. Chronic kidney disease was identified by a GFR calculated by the Modification of Diet in Renal Disease formula < 60 mL/min per 1.73 m². COPD was identified by forced expiratory volume in 1 s < 1 liter or long-term use of bronchodilators, steroids or oxygen for lung disease. Pulmonary hypertension was defined as an estimated systolic pulmonary pressure ≥ 60 mmHg with echocardiography. The surgical risk was estimated by the logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation).^[17]

In-hospital events measured were: all-cause death, car-

diac death (including deaths not clearly due to extra-cardiac causes), cerebrovascular events (stroke, transient ischemic attack), myocardial infarction, acute aortic regurgitation, and vascular complications. Stroke was classified as disabling or not disabling based on the use of the modified Rankin Scale. Vascular complications were defined major (leading to death, life-threatening or major bleeding, permanent damage or requiring surgery) or minor (including percutaneous closure device failure).

The study protocol has been approved by the local ethics committee and all patients signed written informed consent.

2.3 Statistical analysis

Continuous variables were expressed as mean \pm SD and categorical variables were presented as frequencies and percentages. Comparisons between groups were performed with Chi-square test and Student's *t* test for categorical and continuous variables, respectively. Univariate and multivariable logistic regression analyses, including variables listed in Tables 1 and Table 2, were performed in order to evaluate factors associated with definitive treatment of aortic stenosis after BAV. Multivariable logistic regression analyses were conducted on variables with $P < 0.1$ at univariate analysis. Multicollinearity amongst variables was detected by means of Spearman correlation test. Models building follow a backward-stepwise approach, the test of term significance is the Wald chi-square test with cutoff P value of 0.1 for removal and 0.05 for addition. For the multivariable logistic regression the model discrimination and calibration were reported. Model discrimination was assessed calculating the Area under the Receiver Operator Characteristic (ROC) curve, whereas model calibration has been determined by Hosmer-Lemeshow (H-L) test. All tests were 2-sided and a P value less than 0.05 was considered statistical significant. Analyses were performed with Stata/SE 12.1 statistical software (StataCorp LP, College Station, TX, USA).

3 Results

Between July 2007 and December 2012, 645 patients underwent a first BAV at our institution. In 202 cases, indication for the procedure was BTB, which represents the focus of this study. Study flow is reported in Figure 1. Demographics, clinical history and baseline characteristics are reported in Table 1. Patient high-risk profile is confirmed by age (81 ± 7 years) and high prevalence of comorbidity, including coronary artery disease (43.1%), previous cardiac surgery (9.9%), severe renal disease (27.2%), COPD (29.2%) and high logistic EuroSCORE ($23.5\% \pm 15.3\%$).

Table 1. Baseline characteristics.

Variable	All patients (n = 202)
Demographics	
Age, yrs	81 \pm 7
Male gender	89 (44.1)
BMI, kg/m ²	24.9 \pm 4.7
BMI < 20, kg/m ² *	24 (11.9%)
Risk factors	
Diabetes	63 (31.2%)
Hypertension	161 (79.7%)
Hypercholesterolemia	109 (54.0%)
Clinical history	
Previous myocardial infarction	51 (25.2%)
Previous percutaneous coronary intervention	32 (15.8%)
Previous coronary artery bypass graft	18 (8.9%)
Previous cardiac surgery	20 (9.9%)
Previous cerebrovascular accident	28 (13.9%)
Comorbidity	
Coronary artery disease	87 (43.1%)
Chronic kidney disease	163 (80.7%)
GFR < 30 mL/min per 1.73m ²	55 (27.2%)
Chronic obstructive pulmonary disease	261 (29.2%)
Pulmonary hypertension	5 (13.9%)
Clinical presentation	
Dyspnea	189 (93.6%)
NYHA I-II	28 (14.8%)
NYHA III-IV	161 (85.2%)
Stable angina	47 (23.3%)
Syncope	21 (10.4%)
Cardiogenic shock	9 (4.5%)
Hemodynamic instability	103 (51.0%)
Logistic EuroSCORE, %	23.4 \pm 15.2

Data are presented as mean \pm SD or *n* (%). *Valve Academic Research Consortium-2 cutoff. BMI: body mass index; EuroSCORE: European system for cardiac operative risk evaluation; GFR: glomerular filtration rate; NYHA: New York Heart Association.

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

	Before-BAV (n = 202)	After-BAV (n = 148)	<i>P</i>
AVA, cm ²	0.66 \pm 0.17	0.84 \pm 0.24	< 0.01
Average transvalvular gradient, mmHg	47 \pm 17	33 \pm 14	< 0.01
Max gradient, mmHg	76 \pm 27	55 \pm 23	< 0.01
Aortic regurgitation grade			< 0.01
\leq 1	148 (73.3%)	88 (59.4%)	
2	48 (24.7%)	53 (35.8%)	
\geq 3	6 (3.0%)	7 (4.7%)	
Mitral valve regurgitation			0.51
\leq 1	119 (58.9%)	89 (60.1%)	
2	50 (24.7%)	42 (28.4%)	
\geq 3	33 (16.3%)	17 (11.5%)	
LVEF, %	50 \pm 17	51 \pm 16	0.47

Data are presented as mean \pm SD or *n* (%). AVA: aortic valve area; BAV: balloon aortic valvuloplasty; LVEF: left ventricular ejection fraction.

Table 2 summarizes echocardiography data before and after BAV. Mean trans-valvular gradient decreased from 47 ± 17 mmHg to 33 ± 14 mmHg and aortic valve area (AVA) increased from 0.66 ± 0.17 mm² to 0.84 ± 0.24 mm². Nine patients (4.5%) died before hospital discharge, of whom the vast majority (eight patients) had hemodynamic instability at admission. The incidence of other complications was overall low (Table 3). All 193 surviving patients were re-evaluated at the outpatient clinic and by the heart team around one month later.

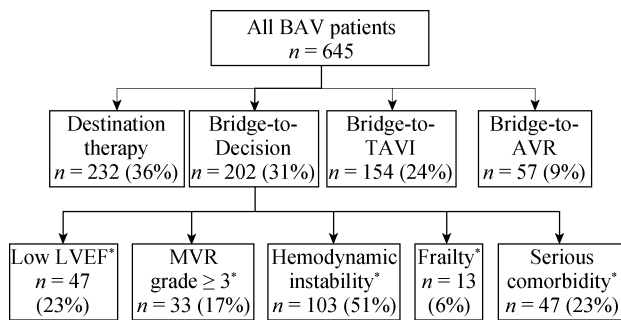


Figure 1. Study flow. Selection and classification of patients who underwent BAV as bridge-to-decision. AVR: aortic valve replacement; BAV: balloon aortic valvuloplasty; LVEF: left ventricular ejection fraction; MVR: mitral valve regurgitation; TAVI: transcatheter aortic valve implantation. *Forty-one patients presents > 1 conditions.

Table 3. In-hospital outcome.

	All patients
Death	9 (4.5%)
Cardiac	8 (4.0%)
Non cardiac	1 (0.5%)
Acute myocardial infarction	0
Cerebrovascular accident	2 (1.0%)
Transient ischemic attack	0
Stroke	2 (1.0%)
Disabling	1 (0.5%)
Non disabling	1 (0.5%)
Vascular complications	8 (4.0%)
Major	1 (0.5%)
Minor	7 (3.5%)
Vascular complication description	
Access-site hematoma	5 (2.5%)
Retroperitoneal hematoma	0
Artero-venous fistula	0
Femoral dissection	1 (0.5%)
Femoral pseudo-aneurysm	2 (1.0%)
Thrombosis	0
Acute aortic regurgitation	2 (1.0%)

Data are presented as n (%).

3.1 Patients with low LVEF

A significant improvement in LVEF was observed in 30/44 surviving patients (68.2%). Average LVEF after BAV was $38\% \pm 7\%$ in patients who recovered vs. $26\% \pm 4\%$ ($P < 0.01$) in those who did not. There were no significant differences in demographics and clinical history, including previous myocardial infarction, between patients who recovered LVEF and those who did not (Online data supplement Table 1). Baseline LVEF was also similar between groups (28 ± 4 mmHg vs. 26 ± 3 mmHg, respectively, $P = 0.27$), as well as baseline AVA (0.65 ± 0.17 mm² vs. 0.64 ± 0.15 mm², $P = 0.83$). Conversely, there was a significant difference in baseline transvalvular gradients (mean gradient 42 ± 16 mmHg vs. 31 ± 8 mmHg, $P = 0.03$). After one month, patients who recovered showed similar AVA (0.80 ± 0.23 mm² vs. 0.88 ± 0.21 mm², $P = 0.30$) but higher gradients (mean gradient 33 ± 15 mmHg vs. 22 ± 7 mmHg, $P < 0.01$). Among patients with LVEF recovery 96.7% were candidates for definitive treatment (53.4% TAVI, 43.3% AVR) vs. 21.4% (all TAVI) in patients who did not show LVEF recovery ($P < 0.001$) (Figure 2).

3.2 Patients with MVR

Within the 33 patients with MVR grade ≥ 3 , a significant reduction of MVR grade was observed in 17 (51.5%), whereas in 16 patients (48.5%) there were no relevant

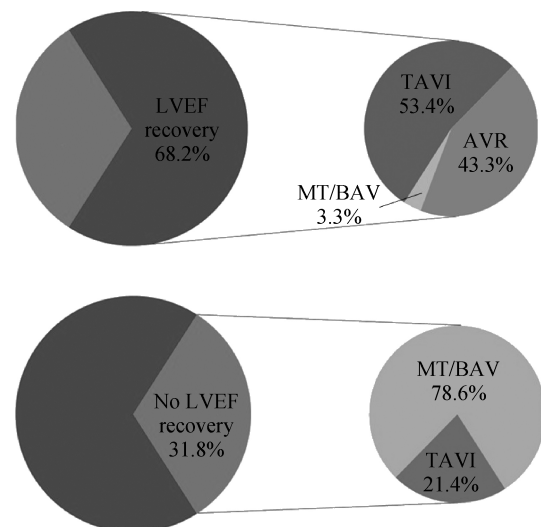


Figure 2. Effect of bridge-to-decision BAV on decision making in patients with reduced LVEF. Proportion of patients with or without significant recover of LVEF who were candidate to different definitive treatment of aortic stenosis after BAV. AVR: aortic valve replacement; BAV: balloon aortic valvuloplasty; LVEF: left ventricular ejection fraction; MT/BAV: medical treatment/repeated balloon aortic valvuloplasty; TAVI: transcatheter aortic valve implantation.

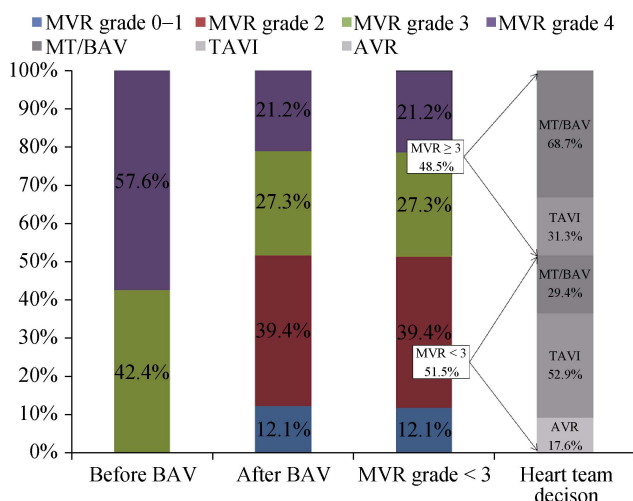


Figure 3. Effect of bridge-to-decision BAV on decision making in patients with moderate to severe MVR. Changes in MVR grade after BAV and effect on final decision making by the heart team. AVR: aortic valve replacement; BAV: balloon aortic valvuloplasty; MT/BAV: medical treatment/repeated balloon aortic valvuloplasty; MVR: mitral valve regurgitation; TAVI: transcatheter aortic valve implantation.

changes. There were no significant differences between patients who improved MVR to a grade < 3 and those who did not, with the notable exception of AVA after BAV ($0.89 \pm 0.21 \text{ mm}^2$ vs. $0.72 \pm 0.17 \text{ mm}^2$, $P = 0.045$) (Online data supplement Table 2). Changes in MVR grade and final heart team decision are illustrated in Figure 3. Overall, 70.5% of patients with MVR grade reduction were addressed to definitive treatment (52.9% TAVI, 17.6% AVR) vs. 31.3% of patients without MVR grade improvement ($P = 0.02$).

3.3 Patients with hemodynamic instability

Among 103 patients, 9 (8.7%) presented with cardiogenic shock, 44 (42.7%) with acute pulmonary edema at the time of BAV, and 50 (48.6%) with NYHA class IV. Eight patients (7.8%) died in-hospital. Among the 95 remaining patients, 21 (22.1%) were candidates for AVR, 57 (60%) for TAVI and 17 (17.9%) for MT/BAV.

3.4 Frailty

Thirteen patients were classified as fragile according to previously mentioned criteria. They must be fragile enough to be considered ineligible for definitive treatment at the time of BTB BAV but not so fragile to be directly addressed to palliative care. Among them, 6 patients (46.1%) were candidates for TAVI, 3 for AVR (23.1%) and 4 (30.8%) for MT/BAV.

3.5 Comorbidity

Among 47 patients with serious comorbidity, 34 (72.3%)

received BAV as bridge to urgent non cardiac surgery, 5 had severe pulmonary hypertension (10.6%), and 8 patients had multiple comorbidities (17%). After BTB BAV, 25 (53.2%) were addressed to MT/BAV, 7 to TAVI (14.9%), and 15 (31.9%) to AVR.

3.6 Whole BTB population

Among 193 patients with BTB BAV who received a second heart team evaluation, 49 (25.4%) were finally deemed eligible for AVR, 91 (47.2%) for TAVI, and the remaining 53 (27.5%) were not deemed eligible to definitive treatment and were candidates for MT/BAV (Figure 4).

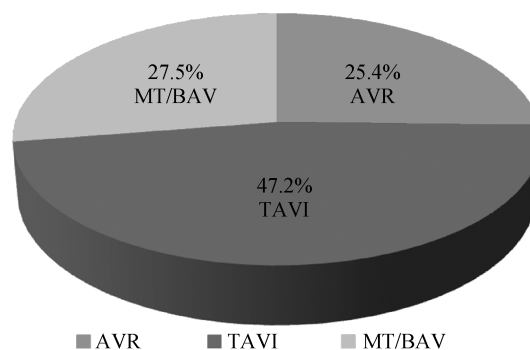


Figure 4. Effect of bridge-to-decision BAV on decision making in the whole study population. Outcome of the second heart team evaluation in patients who underwent bridge-to-decision BAV. AVR: aortic valve replacement; BAV: balloon aortic valvuloplasty; MT/BAV: medical treatment/repeated balloon aortic valvuloplasty; TAVI: transcatheter aortic valve implantation.

At multivariable analyses (C statistic = 0.74; Hosmer and Lemeshow goodness-of-fit test $P = 0.23$), the independent predictors for definitive treatment of AS (either TAVI or AVR) were age, BMI, coronary artery disease, average transvalvular gradient before BAV and hemodynamic instability (Table 4).

4 Discussion

This study explored the role of BAV as bridge-to-decision in high-risk patients with severe AS who presented cardiac or extra-cardiac conditions necessitating further evaluation by the heart team. The rationale behind such a strategy is twofold: helping the heart team to choose the best therapeutic option for each patient; avoiding futile procedures in patients who would probably not have prognostic benefit from definitive treatment of AS. Our investigation suggests that, in this patient population, BTB BAV is safe and might have relevant impact on final decision-making. More specifically, BAV proved very useful for evaluating left ventricular contractile reserve and mitral regurgitation

Table 4. Independent predictors for definitive treatment of aortic stenosis after balloon aortic valvuloplasty.

Variable	Univariate analysis			Multivariable analysis*		
	OR	95% CI	P	OR	95% CI	P
Age	0.95	0.90–0.99	0.02	0.93	0.88–0.99	0.021
BMI	1.07	1.00–1.14	0.04	1.09	1.01–1.18	0.028
Coronary artery disease	3.74	1.89–7.38	0.0001	3.37	1.58–7.21	0.002
Chronic kidney disease	0.43	0.18–1.03	0.06			
Dyspnea	2.84	0.91–8.84	0.07			
Stable angina	2.19	0.99–4.88	0.05			
Baseline MVR grade ≥ 3	0.40	0.19–0.85	0.018			
Hypercholesterolemia	2.22	1.21–4.08	0.01			
Baseline average transvalvular gradient	1.02	1.00–1.04	0.09	1.03	1.00–1.05	0.017
Hemodynamic instability	1.86	1.01–3.42	0.05	2.54	1.21–5.33	0.014

* C statistic = 0.74; Hosmer and Lemeshow goodness-of-fit test $P = 0.23$. BMI: body mass index; MVR: mitral valve regurgitation.

grade reduction, and their association with clinical improvement. In haemodynamically unstable patients, BAV can support patient's recovery and lead to indication of definitive treatment on an elective basis in many patients. Finally, in very fragile patients and those with relevant extra-cardiac comorbidity, BAV may help predicting functional recovery after definitive treatment and be a valid tool to avoid or reduce the occurrence of futile procedures.

There is growing utilization of BAV as a bridge to TAVI or AVR.^[18–23] However, within this patient group, roughly two additional subgroups can be distinguished: (1) patients undergoing BAV to palliate symptoms and reducing operative risk while they await definitive therapy (“true” bridge-to-TAVI or bridge-to-AVR); (2) patients undergoing BAV as a “bridge-to-decision”, because there is the need to assess the potential benefit of valve replacement before committing to the procedural risk, or to evaluate recover from associated conditions which have serious prognostic implications. Our study is the first investigation specifically focused on this last peculiar BAV indication.

Whilst many high-risk patients can be safely addressed to AVR^[24] or TAVI^[5–7] following accurate multidisciplinary evaluation, in some instances additional information may be needed to complete the diagnostic workout. Indeed multiple factors influence symptoms, life expectancy and final outcomes of invasive procedures in elderly patients with severe AS and relevant comorbidity. Thus, not surprisingly, our study population was quite heterogeneous. In this context, the second heart team evaluation around one month after BTB BAV generated a true differentiation of final therapeutic decision between TAVI, AVR and MT/BAV, and our data show that clinical and/or laboratory changes occurred after BTB BAV were actually meaningful for decision-making. For example, patients who showed significant LVEF recovery and/or MVR grade reduction after BTB

BAV were significantly more likely to be candidates for definitive AS treatment in comparison with patients not showing significant changes. Likewise, BTB BAV was very helpful in patients with hemodynamic instability, with the vast majority of patients (75.7%) successfully stabilized and candidates for definitive treatments. More challenging is the interpretation of results in patients classified as fragile or with relevant comorbidity, maybe because this post-hoc classification could only partially rely on objective data. Yet, 69.2% of very fragile patients and 46.8% of the patients with severe or multiple comorbidity were finally recommended for definitive AS treatment, mainly on the ground of some clinical improvement.

Previous studies have shown an improvement of LVEF after BAV,^[25] and an association between LVEF recovery after BAV and prognosis post-TAVI.^[26,27] Dobutamine stress echocardiography is commonly recommended to evaluate contractile reserve in patients with severe AS and reduced LVEF undergoing surgical or percutaneous aortic valve replacement. Our data show a higher pre-BAV average gradient in those patients with low LVEF who benefited a recovery, possibly a sign of concealed contractile reserve. Nevertheless, BAV may provide complimentary information beyond contractile reserve.^[26] In our view, this is particularly evident when there are other concomitant conditions potentially associated with adverse prognosis or lack of symptoms relief. It has been previously reported that nearly half of patients with severe AS and coexistent MVR showed a reduction in the magnitude of MVR after BAV,^[28] our study reproduced very closely those figures (51.5% significant MVR reduction). A reduction in pulmonary artery systolic pressure can be observed in around half of the patients.^[29] Additional insights can be provided by BTB BAV when an unstable hemodynamic state may preclude a thorough patient evaluation. Finally, in patients with very ad-

vanced age or serious comorbid disease, including frailty, cognitive alteration, severe lung disease, BTD BAV may be important to estimate the potential benefit of valve replacement. In fact, severe comorbidity is often determinant to deny AVR, but is also strongly affecting mid- and long-term prognosis after TAVI,^[27,30,31] and BTD BAV may be a useful tool to improve risk stratification.

This is a nonrandomized, single-center study, and all our findings should be interpreted cautiously. Study population was quite heterogeneous, and classification into subgroups of interest was arbitrarily done retrospectively. Definition of “significant improvement” for all patients was subject to multiple confounding factors which are difficult to measure and report objectively, and this was especially true for patients with low LVEF, frailty and serious comorbidity. Another weak point of the study is that, despite demonstration of safety of a bridge-to-decision BAV strategy, the selection of the appropriate therapy remains a difficult issue even after BAV and might be subject to important variation from a Heart Team to another. Even recognizing that more data occur, consistency with findings from other investigations and the relatively large number of patients included in the present analysis is noteworthy.

In conclusion, BAV could be considered as bridge-to-decision in high-risk patients with severe aortic stenosis who cannot be immediately candidate to definitive percutaneous of surgical treatment.

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