Reappraisal of percutaneous aortic balloon valvuloplasty as a preliminary treatment strategy in the transcatheter aortic valve implantation era

Claire-Marie Tissot¹, MD; David Attias¹, MD; Dominique Himbert^{1*}, MD; Gregory Ducrocq¹, MD; Bernard Iung¹, MD; Marie-Pierre Dilly², MD; Jean-Michel Juliard¹, MD, Laurent Lepage³, MD, Delphine Détaint¹, MD, David Messika-Zeitoun¹, MD, PhD, Patrick Nataf³, MD, Alec Vahanian¹, MD

1. Department of Cardiology, Assistance Publique-Hôpitaux de Paris (AP-HP), Bichat-Claude Bernard Hospital, Paris, France; 2. Department of Anaesthesiology, Assistance Publique-Hôpitaux de Paris (AP-HP), Bichat-Claude Bernard Hospital, Paris, France; 3. Cardiovascular Surgery, Assistance Publique-Hôpitaux de Paris (AP-HP), Bichat-Claude Bernard Hospital, Paris, France

KEYWORDS

aortic stenosis

- percutaneous aortic balloon valvuloplasty
- aortic valve replacement
- transcatheter aortic valve implantation

Abstract

Aims: To assess the results of percutaneous aortic balloon valvuloplasty (PABV) as a potential bridge to further intervention in patients referred for transcatheter aortic valve implantation (TAVI).

Methods and results: Two hundred and fifty-three patients referred for TAVI were studied: 41 (16%) were considered transiently unsuitable for either aortic valve replacement (AVR) or TAVI and underwent PABV as a bridge to intervention. In the others, primary TAVI or AVR was performed in 140 cases, and medical therapy alone in 72. The overall population was at high risk: 82 ± 8 years, logistic EuroSCORE: $28\pm16\%$, STS score: $16\pm10\%$. There was no PABV-related death. Twenty-three patients underwent secondary TAVI (n=19) or AVR (n=4), 18 did not undergo further intervention. One and two year survival rates were respectively $94\pm5\%$ and $85\pm10\%$ after bridge PABV, and 33 ± 11 and $6\pm5\%$ after PABV alone. There was no difference in survival between the primary TAVI / AVR and bridge PABV (p=0.08), and between medical treatment and PABV alone (p=0.36).

Conclusion: In high-risk patients with aortic stenosis and temporary contraindications to AVR or TAVI, PABV may be used as a bridge to intervention with good mid-term outcomes. In others, PABV can be safely used but is associated with a poor outcome.

* Corresponding author: Department of Cardiology, Bichat Hospital, 46, rue Henri Huchard, 75018 Paris, France E-mail: dominique.himbert@bch.aphp.fr



Abbreviations

AR	aortic regurgitation
AS	aortic stenosis
AVA	aortic valve area
AVR	aortic valve replacement
CI	contraindication
COPD	chronic obstructive pulmonary disease
LVEF	left ventricular ejection fraction
MI	myocardial infarction
NYHA	New York Heart Association
PABV	percutaneous aortic balloon valvuloplasty
PCI	percutaneous coronary intervention
SD	standard deviation
SPAP	systolic pulmonary artery pressure
STS-PROM	Society of Thoracic Surgeons Predicted Risk of
	Mortality
TA	transapical
TAVI	transcatheter aortic valve implantation
TF	transfemoral

Introduction

Since its introduction for treating aortic stenosis (AS) more than 20 years ago, percutaneous aortic balloon valvuloplasty (PABV) has had limited indications because of its poor efficacy in improving the natural history of the disease.¹⁻³ However, this technique has experienced a revival with the development of transcatheter aortic valve implantation (TAVI), as part of the procedure.^{4,5} Furthermore, it may represent an interesting option as a bridge to TAVI or surgical aortic valve replacement (AVR).⁶

The aim of this study was to describe the current use and results of PABV in high-risk patients referred for the management of severe and symptomatic AS by TAVI.

Methods

From October 2006 to September 2009, all patients consecutively referred for TAVI underwent a screening process and multidisciplinary clinical evaluation, transthoracic and, if necessary, transesophageal echocardiography, coronary angiography, aortic and femoroiliac angiography, and multislice computed tomography. The decision to perform TAVI was taken in patients with severe symptomatic AS; contraindications to, or high risk for AVR (Euro-SCORE \geq 20% or STS-PROM \geq 10%); a life expectancy >1 year; an anatomy suitable for intervention; no need for coronary bypass surgery.7 In patients with contraindications to TAVI, AVR was reconsidered if the operative risk was not deemed prohibitive. In patients who were too frail, or those with technical contraindications to any invasive intervention, or with comorbidities that limited short-term life expectancy or precluded future quality of life, a simple medical treatment was decided upon. Finally, PABV was considered as a potential bridge to further intervention in patients with either transient or doubtful contraindications to both TAVI and AVR, for example in those whose clinical condition did not allow screening upon admission because of haemodynamic instability, such as cardiogenic shock (arterial hypotension below 90 mmHg, unresponsive to inotropic vasopressors agents, associated with clinical and biological signs of peripheral hypoperfusion or progressive multiorgan failure) or severe pulmonary oedema requiring invasive or non-invasive ventilation. Among the latter patients, some of them actually underwent secondary TAVI or AVR (bridge PABV group), and others had no further intervention (PABV alone group).

Procedures were usually performed under local anaesthesia, with fluoroscopic guidance, via the transfemoral retrograde approach. However, in emergent situations such as cardiogenic shock, 12 patients were treated after oro-tracheal intubation and under general anaesthesia. After placement of a 10 or 12 Fr sheath, the native valve was crossed and a 0.035" extra-stiff 2.6 m length J curved wire was placed at the apex of the left ventricle. Then, a valvuloplasty balloon (Cristal; Balt, Montmorency, France or Nucleus; Numed, Hopkinton, NY, USA) was brought to the aortic valve. The size of the balloon diameter was chosen according to the measurement of the annulus diameter by echocardiography (ratio 1/1). In most cases, a rapid right ventricular pacing was used to stabilise the balloon during inflation. At the end of the procedure, patients were transferred to the intensive care unit.

Hospital clinical and echocardiographic data were prospectively obtained before discharge. All adverse events were recorded. After the hospital phase, clinical follow-up was obtained in all survivors at 1-3 months, 6 months, 1 year, and then annually.

Continuous data were expressed as mean±SD, except for the delay to TAVI or AVR after PABV, and for the length of follow-up, which were expressed as median with $25^{th}-75^{th}$ percentiles. The Mann-Whitney U test was used to compare continuous variables in the different groups, and categorical variables were compared by the chi-square or Fisher exact test. Multiple group comparisons used one-way analysis of variance or chi-square test and, when significant, 2-by-2 subgroup comparisons were performed using the Bonferroni correction. Survival rates were estimated using the Kaplan-Meier method and were compared using the log-rank test. All tests were two-sided. A *p*-value <0.05 was considered to indicate a statistically significant difference. Statistical analysis was performed using statistical software Statistica version 5.0; Statsoft Inc., Tulsa, OK, USA.

Results

The management of the study population is detailed in **Figure 1**. Of the 253 patients at high risk or with contraindications to surgery who were referred for TAVI, 41 (16%) underwent PABV because of: unstable haemodynamic state requiring urgent intervention and precluding screening process in 27 cases (of whom 12 were rescue PABV for cardiogenic shock); restricted availability of the device in six cases; associated cancer requiring further explorations in four cases; therapeutic test for contentious clinical presentations in three cases (combination with severe lung disease in two cases; uncertainty over the degree of AS in one); associated unstable coronary artery disease requiring urgent percutaneous revascularisation combined with PABV in one case. Among the other patients referred for TAVI, 140 patients underwent primary TAVI (n=113, 45%) or AVR



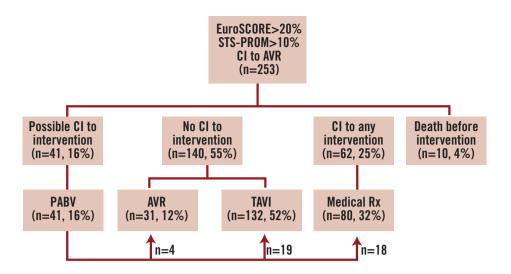


Figure 1. Management of high-risk patients with severe symptomatic aortic stenosis. Flow chart of 253 high-risk patients referred for transcatheter aortic valve implantation. AVR: aortic valve replacement; CI: contraindication; PABV: percutaneous aortic balloon valvuloplasty; TA: transapical; TAVI: transcatheter aortic valve implantation TF: transfemoral

(n=27, 10%), 62 (25%) received no intervention because of general or technical contraindications to any intervention, and 10 (4%) died before intervention.

The characteristics of the whole population are presented in **Table 1**. Overall, patients treated by PABV had a higher risk profile than those who were treated using primary TAVI or AVR, regarding the severity of NYHA class, the presence of renal failure and other extra-cardiac comorbidities, which was reflected by higher logistic EuroSCORE and the STS scores. Conversely, the echocardio-graphic parameters addressing the severity of the AS and left ventricular function did not significantly differ between the groups. The characteristics of the patients treated by bridge PABV and PABV alone are presented in **Table 2**. There was no difference between the two groups except for renal failure, which was more frequent in patients treated by PABV alone than by bridge PABV, and the trend towards higher risk scores in the PABV alone group.

Of the 41 patients who underwent PABV, 23 underwent secondary elective TAVI (n=19: TF, n=15, TA, n=4) or AVR (n=4, bioprostheses), while 18 finally did not undergo further intervention because of technical contraindications to both transfemoral and transapical TAVI in 10 cases (too large aortic annular diameters: n=9, severe respiratory failure: n=1), general contraindications secondarily detected by further geriatric evaluation in five (disseminated cancer: n=3, frailty: n=1, severe cognitive disorder: n=1), in-hospital death before intervention in two cases and patient refusal in one case. The median delay between bridge PABV and TAVI or AVR was 48 days (4-202): it was <10 days in three patients (after rescue PABV), 10 to 30 days in six, one to six months in eight, and >6 months in six. It was significantly shorter in patients with initial cardiogenic shock than in stable patients (median 12 days [8-28] versus 145 days [35-442], respectively, p= 0.002).

Early outcomes are detailed in **Table 3**. PABV was successfully performed in all the cases and complications were rare. The most frequent complication was the occurrence of new complete atrio-

ventricular blocks requiring pace-maker implantation (7%). There was one vascular complication (2%) in an 87-year-old woman who presented a voluminous haematoma at the femoral puncture site requiring surgical drainage. There was neither stroke nor myocardial infarction. No death occurred during PABV. Haemodynamic results of PABV are presented in **Table 4**. All parameters were significantly improved by the procedure and, overall, there was no significant change in the AR grade. There was only one grade 3 AR, with no early clinical consequences. When it was initially <40%, LVEF increased in all the cases after PABV (**Figure 2**). Thirty-day mortality was 15% (6/41) consisting of four in-hospital deaths and

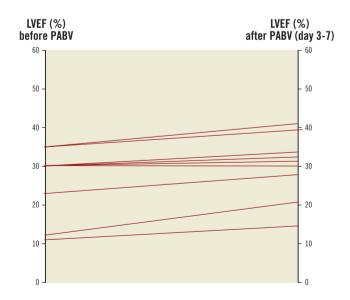


Figure 2. Percutaneous aortic balloon valvuloplasty and ventricular function. Impact of percutaneous aortic balloon valvuloplasty on depressed left ventricular ejection fraction (<40%). LVEF: left ventricular ejection fraction; PABV: percutaneous aortic balloon valvuloplasty



	Overall (n=253)	Primary TAVI or AVR (n=140)	PABV (n=41)	No intervention* (n=72)	p
Age (years, mean±SD)	82±8	82±8	81±8	83±9	0.27
Female gender	122 (48)	64 (46)	19 (46)	39 (54)	0.49
NYHA class			¶‡		0.03
11	10 (4)	5 (4)	0	5 (7)	
III	147 (58)	91 (65)	15 (37)	41 (57)	
IV	96 (38)	44 (31)	26 (63)	26 (36)	
Coronary artery disease					
Previous MI	134 (61)	83 (60)	24 (67)	27 (60)	0.74
Previous PCI	55 (22)	29 (21)	11 (27)	15 (21)	0.69
Previous CABG	52 (21)	30 (21)	10 (24)	12 (17)	0.58
Peripheral artery disease	89 (35)	55 (39)	12 (29)	22 (31)	0.31
Renal failure	102 (40)	43 (31)	24 (59)¶	35 (49)	0.001
Severe COPD	80 (32)	48 (34)	13 (32)	19 (26)	0.50
Cancer	64 (25)	35 (25)	13 (32)	16 (22)	0.53
Porcelain aorta	25 (10)	17 (12)	4 (10)	4 (6)	0.42
≥2 comorbidities	152 (60)	76 (54)	30 (73)	46 (64)	0.07
Aortic valve area		1			
cm ²	0.69±0.18	0.69±0.18	0.66±0.2	0.69±0.17	0.56
cm²/m²	0.40±0.10	0.40±0.1	0.39±0.09	0.40±0.11	0.76
Mean gradient (mmHg)	48±16	50±16	46±14	45±16	0.07
LVEF (%)	48±16	51±15	44±17	45±16	0.01
<30%	33 (13)	11 (8)	6 (15)	16 (22)	0.01
SPAP (mmHg)	50±14	48±13	56±17¶	52±14	0.009
Logistic EuroSCORE (%)					
Mean±SD	28±16	25±12	37±22¶	31±17	<0.0001
Range	3-90	3-74	10-90	3-72	
STS-PROM (%)					
Mean±SD	16±10	15±8	22±12¶	15±9	0.0015
Range	3-62	3-41	7-62	3-46	

*Including the 10 patients who died before intervention; ¶: p<0.05 between PABV and primary TAVI or AVR; ‡ p<0.05 between PABV and medical treatment; Values are expressed as n (%) unless otherwise stated. CABG: coronary artery bypass grafting; CI: contraindication; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; SD: standard deviation; SPAP: systolic pulmonary artery pressure; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; TAVI: transcatheter aortic valve implantation

two post-discharge deaths at day 25 and day 28 from delayed cardiogenic shock; all the deaths were observed in the PABV alone group. All the in-hospital deaths were observed in the 12 patients with initial cardiogenic shock: three patients were not improved by PABV and died promptly from multi-organ failure while one died at day 18 from pulmonary infection. The eight other patients with cardiogenic shock treated by rescue PABV improved and were subsequently treated by TAVI in four cases and by AVR in two cases, while two others did not undergo further intervention. As a result, 30-day mortality was 33% (4/12) for patients treated by rescue PABV for cardiogenic shock. Of the 37 patients who were discharged alive from hospital, clinical improvement (decrease in ≥ 1 NYHA class) was present in 33 patients (89%); three patients (8%) remained in class III, one (3%) in class IV. Thirty-day mortality was 12% (17/140) in patients treated by primary TAVI or AVR, and 14% (10/72) in those receiving a simple medical treatment.

Median follow-up duration was 10 months (2-18) in patients who underwent primary PABV. The Kaplan Meier survival curves of all patients' subsets are presented in **Figure 3**. One and 2-year survival rates were respectively 94 ± 5 % and 85 ± 10 % after bridge PABV, and 33 ± 11 % and 6 ± 5 % after PABV alone. The causes of deaths are detailed in **Table 5**. All but two of them were observed in the PABV alone group and they were mostly due to delayed progressive cardiac failure. Of the 27 patients who presented initially with haemodynamic instability and finally underwent TAVI or AVR, one died at day 421 (heart failure). There was no late death in patients



Table 2. Baseline characteristics of the patients treated by percutaneous aortic balloon valvuloplasty.

		,	
	Bridge to TAVI or AVR (n=23)	PABV alone (n=18)	р
Age (years, mean±SD)	79±8	83±8	0.12
Female sex	11 (48)	8 (44)	0.83
NYHA class			0.36
11	0	0	
	7 (30)	8 (44)	
IV	16 (70)	10 (56)	
Cardiogenic shock	6 (26)	6 (33)	0.61
Coronary artery disease	13 (57)	11 (85)	0.14
Previous MI	4 (17)	7 (39)	0.16
Previous PCI	6 (26)	4 (22)	1
Previous CABG	6 (26)	5 (28)	1
Peripheral artery disease	6 (26)	6 (33)	0.61
Renal failure	10 (43)	14 (78)	0.05
Severe COPD	8 (35)	5 (28)	0.74
Cancer	8 (35)	5 (28)	0.74
Porcelain aorta	4 (17)	0	0.12
≥2 comorbidities	16 (70)	14 (78)	0.73
Aortic valve area			
cm ²	0.71±0.19	0.59±0.19	0.05
cm²/m²	0.41±0.1	0.36±0.08	0.11
Mean gradient (mmHg)	48±13	43±15	0.21
LVEF (%)	49±17	40±15	0.08
< 30%	3 (13)	3 (17)	1
Logistic EuroSCORE (%)			
Mean±SD	35±21	39±24	0.56
Range	10-90	10-86	
STS-PROM (%)			
Mean (SD	19±10	24±14	0.24
Range	8-47	7-62	

Values are expressed as n (%) unless otherwise stated. AVR: aortic valve replacement; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; SD: standard deviation; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; TAVI: transcatheter aortic valve implantation

who initially presented with cardiogenic shock. Two-year survival rates were $65\pm7\%$ after primary TAVI or conventional AVR, and $17\pm7\%$ after medical treatment alone. Overall, there was no significant difference in survival rates between the primary TAVI/AVR and bridge PABV groups on one hand (p=0.08), and the medical treatment and PABV alone groups on the other (p=0.36).

Discussion

Very few data exist on the use of PABV as a bridge therapy to TAVI or AVR.⁸⁻¹⁰ In patients with temporary or doubtful contraindications

Table 3. 30-day outcomes in patients treated by percutaneousaortic balloon valvuloplasty.

	Overall (n=41)	Bridge to intervention (n=23)	PABV alone (n=18)	р
Major vascular complications	1 (2)	0	1 (6)	0.44
Heart block*	3 (7)	1 (4)	2 (11)	0.57
Mortality	6 (15)	0	6 (33)	0.04
Per-procedure	0	0	0	
30-day cardiac	5 (12)	0	5 (27)	0.01
30-day non-cardiac	1 (3)	0	1 (6)	0.44
	(0()	0.0		

Values are expressed as n (%) or mean \pm SD, unless otherwise stated; PABV: percutaneous aortic balloon valvuloplasty; *Requiring definitive pacemaker

Table 4. Echographic findings before and after percutaneous aortic balloon valvuloplasty.

	Before PABV	After PABV	p
AVA			
cm ²	0.66±0.2	0.87±0.18	< 0.001
cm²/m²	0.39±0.09	0.48±0.09	< 0.001
Mean aortic gradient (mm Hg)	46±14	30±13	< 0.001
LVEF (%)	44±17	46±17	0.01
SPAP (mm Hg)	56±17	48±13	0.0001
AR grade			
0	14 (34)	11 (27)	0.57
1	20 (49)	20 (49)	
2	7 (17)	9 (22)	
3	0	1 (2)	

Values are expressed as n (%) unless otherwise stated; AR: aortic regurgitation; AVA: aortic valve area; LVEF: left ventricular ejection fraction; PABV: percutaneous balloon aortic valvuloplasty; SPAP: systolic pulmonary artery pressure

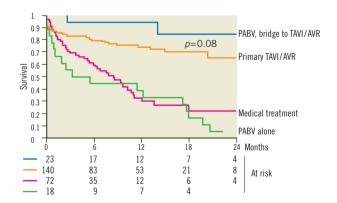


Figure 3. Two-year follow-up survival curves. Kaplan Meier survival curves in 253 high-risk patients with aortic stenosis, according to their treatment. AVR: aortic valve replacement; PABV: percutaneous balloon aortic valvuloplasty; TAVI: transcatheter aortic valve implantation



Table 5. Causes of death in patients treated with percutaneous aortic valvuloplasty.				
Time	PABV	Days to death	Cause of death	
In-hospital	Alone	1	Multi-organ failure	
In-hospital	Alone	3	Multi-organ failure	
In-hospital	Alone	11	Multi-organ failure	
In-hospital	Alone	18	Pulmonary infection	
Post-discharge	Alone	25	Delayed cardiogenic sho	
Post-discharge	Alone	28	Delayed cardiogenic sho	
Post-discharge	Alone	57	Cardiac failure	
Post-discharge	Alone	72	Cardiac failure	
Post-discharge	Bridge	79	Cardiac failure	
Post-discharge	Alone	96	Cardiac failure	

Alone

Alone

Bridge

Alone

Alone

Alone

Alone

Alone

Post-discharge

Post-discharge

Post-discharge

Post-discharge

Post-discharge

Post-discharge

Post-discharge

Post-discharge

with percutaneous

Cardiac failure

Cardiac failure

Cardiac failure

Delayed cardiogenic shock

Renal failure

Cardiac failure

Cardiac failure

Cardiac failure

to both TAVI and AVR, PABV was used as a potential bridge to these interventions. Despite more severe baseline risk profiles, bridge PABV led to short- and mid-term results similar to those observed in patients treated by primary TAVI or AVR. However, when patients could not receive secondary interventions, PABV did not improve the prognosis when compared to medical therapy.

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With the emergence of TAVI, PABV has had to be performed as part of the procedure, which has led to refinement of the materials used and to greater operators' skills^{11,12} In a series on 141 patients, Agatiello et al reported 4% in-hospital mortality, and a 6% nonfatal complications rate.13 These conditions may lead to a reconsideration of PABV to achieve clinical improvement while awaiting the availability of subsequent treatment. Our results confirm that, despite the high-risk profile of these patients, the current use of PABV is reasonably safe. The most frequent event consisted in a 7% rate of new complete atrioventricular blocks requiring a pacemaker, which should be taken into account while interpreting conduction disturbances observed after TAVI.

Contrary to the improvement of procedural safety, haemodynamic efficacy remained limited in the most recent series, with an increase of approximately 40 to 50% in effective orifice area and decrease in mean transvalvular gradient, which is consistent with the present results. However, these modest valve changes were sufficient to achieve significant improvements in LVEF, pulmonary pressures and clinical condition.

Nearly 20 years ago, Cribier et al and Moreno et al pointed out the potential lifesaving role of PABV as an initial treatment for patients with cardiogenic shock due to critical AS.^{14,15} However, patients were younger than in the present series, with a less severe risk profile. The study by Smedira et al also suggested favourable outcomes with this strategy in a series of five patients, and Zimrin et al reported one case of PABV as a bridge to aortic valve bypass with an apicoaortic conduit.^{16,17} More recently, Ussia et al showed that bridging TAVI with PABV was feasible and reasonably safe to offer temporary relief in selected patients with a high chance of periprocedural complications, and Hamid et al tended to the same conclusions.^{8,9} Doguet et al showed that, used as a bridge to AVR, PABV improved cardiac function and the postoperative course.¹⁰ Many patients at high risk are now referred for severe AS18 but TAVI may not be immediately possible due to various reasons: 1) uncertainty as to the degree of aortic stenosis or comorbidities which could preclude reasonable life expectancy. PABV may be an interesting option to allow completion of the work-up before discussing the definitive treatment; 2) very low LVEF or severe pulmonary hypertension, contributing to an increase in the risk of TAVI, as recently shown by Rodés-Cabau et al¹⁹ PABV may improve LVEF and decrease the pulmonary pressures; 3) instability of haemodynamic state, cardiogenic shock or acute coronary syndrome requiring emergent or urgent intervention. Due to availability of the device and logistic considerations, emergent TAVI is not practically doable in most centres, and it has not been evaluated so far. In this situation, TAVI may have been used in combination with left ventricular assistance device; however, need for haemodynamic support has also been identified as a predictor of mortality after TAVI;^{19,20} 4) In the early phase of the program, access to the device may be limited. This accounted for the fact that six patients had to wait more than six months between PABV and TAVI. The patients treated by bridge PABV were at very high risk in this series: 70% of them were in NYHA class IV, 23% were in cardiogenic shock and the average predicted mortality was 35% according to the EuroSCORE, and 19% according to the STS-PROM. This risk profile was much more severe than that of patients who underwent primary TAVI or AVR. Although most patients finally underwent TAVI, clinical improvement achieved by PABV led to opting for conventional AVR in some cases, which was also observed by Kapadia et al.⁶ Despite the more severe risk profile, the outcomes of TAVI or AVR after bridge PABV were similar to primary TAVI or AVR. The significant decrease in pulmonary hypertension and increase in LVEF observed after PABV may have contributed to this result. Also, the fact that patients with decompensated heart failure with no shock and those with severely depressed LVEF were treated by primary TAVI/AVR may explain this finding.

Previously reported results of PABV concluded that results were poor because of the conjunction of a high procedural complications rate, modesty of haemodynamic improvement, and valve restenosis. The study by Bernard et al showed the poor long-term prognosis of patients treated by PABV alone as compared to those treated by AVR (47% versus 83% 2-year survival rates).²¹ As PABV could not change the natural history of AS, its indications were drastically limited as the sole treatment in selected cases to alleviate refractory symp-



toms.^{1-3,22-24} In the present study, PABV was never proposed in patients who had been upfront denied any definitive intervention. However, some patients who were initially treated by PABV with the intention of carrying out further interventions, could not receive them. There was no significant difference in baseline characteristics between patients treated by PABV alone and those treated by bridge PABV. This suggests that differences between both groups mainly related to qualitative, subtle parameters, such as frailty or nature of comorbidities, which could not be immediately detected upon admission and could hardly be quantified and reflected by the predictive risk scores. Overall, the outcomes of patients treated by either PABV alone or medical therapy were similar, and, one and two-year mortality rates were dismal in both groups. The present 33% one-year survival rate observed in patients treated by PABV alone is consistent with those reported by Svensson et al and by Otten et al in US and European experiences in similar populations.^{25,26} This confirms previous findings demonstrating the inability of PABV alone to improve the long-term prognosis of severe symptomatic AS.

Because of its observational nature, the present study does not allow the establishment of a definite reference treatment strategy as regards the use and timing of bridge PABV, which would require a randomised comparison with primary TAVI. This study reflects a single-centre experience of a relatively limited number of patients. However, this allowed a uniform management of the whole study population, as well as comprehensive and prospective data collection with no patient lost to follow-up. As indications for PABV were selected on a case-by-case basis, the study can neither lead to definitely conclude about the usefulness of this strategy, nor to clearly identify the population that might benefit from PABV before TAVI or AVR.

Conclusion

Today, the safety of PABV is good, with improved technical evolutions and operators' experience due to the current diffusion of TAVI. Bridge PABV safely allows for a waiting period before secondary intervention when further explorations are needed, and is clinically effective when haemodynamic instability requires emergent intervention. This strategy achieves good short- and mid-term outcomes, with regard to the severity of the risk profile of patients. As a sole treatment, PABV is unable to interfere with the poor longterm prognosis of the disease. In the future, efforts should be made to better stratify patients' prognosis upon admission and determine those who should undergo bridge PABV and those who could receive primary TAVI.

Conflict of interest statement

D. Himbert and P. Nataf are proctors for Edwards Lifesciences.A. Vahanian and B. Iung received speaker's fees from Edwards Lifesciences. The other authors have no conflict of interest to declare.

References

1. Iung B, Baron G, Butchart EG, Delahaye F, Gohlke-Bärwolf C, Levang OW, Tornos P, Vanoverschelde JL, Vermeer F, Boersma E, Ravaud P, Vahanian A . A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J* 2003;24:1231-43.

2. Bonow RO, Carabello BA, Chatterjee K, de Leon Jr AC, Faxon DP, Freed MD, Gaasch WH, Lytle DW, Nishimura RA, O'Gara PT, O'Rourke RA, Otto CM, Shah PM, Shanewise JS, Smith Jr SC, Jacobs AK, Adams CD, Anderson JL, Antman EM, Fuster V, Halperin JL, Hiratzka LF, Hunt SA, Lytle BW, Page RL, Riegel B. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing Committee to Revise the 1998 guidelines for the management of patients with valvular heart disease) developed in collaboration with the Society of Cardiovascular Anesthesiologists endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. *J Am Coll Cardiol* 2006;48:e1-148.

3. Vahanian A, Baumgartner H, Bax J, Butchart E, Dion R, Filippatos G, Flachskampf F, Hall R, Iung B, Kasprzak J, Nataf P, Tornos P, Torraca L, Wenink A. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. *Eur Heart J* 2007;28:230-68.

4. Cribier A, Eltchaninoff H, Tron C, Bauer F, Agatiello C, Sebagh L, Bash A, Nusimovici D, Litzler PY, Bessou JP, Leon M . Early experience with percutaneous transcatheter implantation of heart valve prosthesis for the treatment of end-stage inoperable patients with calcific aortic stenosis. J Am Coll Cardiol 2004;43:698-703.

5. Webb JG, Altwegg L, Boone RH, Cheung A, Ye S, Lichtenstein S, Lee M, Masson JB, Thompson C, Moss R, Carere R, Munt F, Nietlispach F, Humphries K. Transcatheter aortic valve implantation: impact on clinical and valve-related outcomes. *Circulation* 2009;119:3009-16.

6. Kapadia SR, Goel SS, Svensson L, Roselli E, Savage RM, Wallace L, Sola S, Schoenhagen P, Shishehbor MH, Christofferson R, Halley C, Rodriguez LL, Stewart W, Kalahasti V, Tuzcu EM. Characterization and outcome of patients with severe symptomatic aortic stenosis referred for percutaneous aortic valve replacement. *J Thorac Cardiovasc Surg* 2009;137:1430-5.

7. Vahanian A, Alfieri O, Al-Attar N, Antunes MJ, Bax J, Cormier B, Cribier A, De Jaegere P, Fournial G, Kappetein AP, Kovac J, Ludgate S, Maisano F, Moat N, Mohr FW, Nataf P, Pierard L, Pomar JL, Schofer J, Tornos P, Tuscu M, van Hout B, von Segesser LK, Walther T. Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Association of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *EuroIntervention*. 2008;4:193-9.

8. Ussia GP, Capodanno D, Barbanti M, Scarabelli M, Imme S, Cammarelli V, Mule M, Pistritto A, Aruta P, Tambutino C. Balloon aortic valvuloplasty for severe aortic stenosis as a bridge to high-risk transcatheter aortic valve implantation. *J Invasive Cardiol* 2010;22:161-6.



EuroIntervention 2011;7:49-56

9. Hamid T, Eichhöfer J, Clarke B, Mahadevan V. Aortic balloon valvuloplasty: Is there still a role in high-risk patients in the era of percutaneous aortic valve replacement? *J Interven Cardiol* 2010 DOI 10.1111/j1540-8183.2010.00559.

10. Doguet F, Godin M, Lebreton G, Eltchaninoff H, Cribier A, Bessou JP, Litzler PY. Aortic valve replacement after percutaneous valvuloplasty - An approach in otherwise inoperable patients *Eur J Cardiothorac Surg* 2010, doi: 10.1016/j.ejtes.2010.02.016.

11. Sack S, Kahlert P, Khandanpour S, Naber C, Philip S, Möhlenkamp S, Sievers B, Kälsch H, Erbel R. Revival of an old method with new techniques: balloon aortic valvuloplasty of the calcified aortic stenosis in the elderly. *Clin Res Cardiol* 2008;97:288-97.

12. Hara H, Pedersen WR, Ladich E, Mooney M, Virmani R, Nakamura M, Feldman T, Schwartz RS. Percutaneous balloon aortic valvuloplasty revisited: time for a renaissance? *Circulation* 2007;115:e334-8.

13. Agatiello C, Eltchaninoff H, Tron C, Bauer F, Babalieros V, Nercolini D, Sebagh L, Vochelet F, Tapiero S, Cribier A. Balloon aortic valvuloplasty in the adult. Immediate results and in-hospital complications in the latest series of 141 consecutive patients at the University Hospital of Rouen (2002-2005). *Arch Mal Coeur Vaiss* 2006;99:195-200.

14. Cribier A, Remadi F, Koning R, Rath P, Stix G, Letac B. Emergency balloon valvuloplasty as initial treatment of patients with aortic stenosis and cardiogenic shock. *N Engl J Med* 1992;326:646-51.

15. Moreno PR, Jang IK, Newell JB, Block PC, Palacios IF. The role of percutaneous aortic balloon valvuloplasty in patients with cardiogenic shock and critical aortic stenosis. *J Am Coll Cardiol* 1994;23:1071-5.

16. Smedira NG, Ports TA, Merrick SH, Rankin JS. Balloon aortic valvuloplasty as a bridge to aortic valve replacement in critically ill patients. *Ann Thorac Surg* 1993;55:914-6.

17. Zimrin DA, Reyes PA, Miller KL, Fisher SD, Griffith BP, Gammie JS. Heart failure and "inoperable" aortic stenosis: staged balloon aortic valvuloplasty and aortic valve bypass. *Congest Heart Fail* 2008;14:211-3.

18. Descoutures F, Himbert D, Lepage L, Iung B, Détaint D, Tchetche D, Brochet E, Castier Y, Depoix JP, Nataf P, Vahanian A.

Contemporary surgical or percutaneous management of severe aortic stenosis in the elderly. *Eur Heart J* 2008;29:1410-7.

19. Rodés-Cabau J, Webb JG, Cheung A, Ye J, Dumont E, Feindel CM, Osten M, Natajaran MK, Velianou JL, Martucci G, De Varennes B, Chisholm R, Peterson MD, Lichtenstein SV, Nietlispach F, Doyle D, DeLarochellière R, Teoh K, Chu V, Dancea A, Lachapelle K, Cheema A, Latter D, Horlick E. Transcatheter Aortic Valve Implantation for the Treatment of Severe Symptomatic Aortic Stenosis in Patients at Very High or Prohibitive Surgical Risk Acute and Late Outcomes of the Multicenter Canadian Experience. *J Am Coll Cardiol* 2010;55:1080-90.

20. de Jaegere P, van Dijk LC, Laborde JC, Sianos G, Orenella Ramos FJ, Lighart J, Kappetein AP, vander Ent M, Serruys PW. True percutaneous implantation of the CoreValve aortic valve prosthesis by the combined use of ultrasound guided vascular access, Prostar(R) XL and the TandemHeart(R). *EuroIntervention* 2007;2:500-5.

21. Bernard Y, Etievent J, Mourand JL, Anguenot T, Schiele F, Guseibat M, Bassand JP. Long-term results of percutaneous aortic valvuloplasty compared with aortic valve replacement in patients more than 75 years old. *J Am Coll Cardiol* 1992;20:796-801.

22. Pretre R, Turina MI. Cardiac valve surgery in the octogenarian. *Heart* 2000;83:116-21.

23. Agarwal A, Kini AS, Attanti S, Lee PC, Ashtiani R, Stenheimer AM, Moreno PR, Sharma SK. Results of repeat balloon valvuloplasty for treatment of aortic stenosis in patients aged 59 to 104 years. *Am J Cardiol* 2005;95:43-7.

24. To AC, Zeng I, Coverdale HA. Balloon aortic valvuloplasty in adults - a 10-year review of Auckland's experience. *Heart Lung Circ* 2008;17:468-74.

25. Svensson LG, Dewey T, Kapadia S, Roselli EE, Stewart A, Williams M, Anderson WN, Brown D, Leon M, Lytle B, Moses J, Mack M, Tuczu M, Smith C. United States feasibility study of transcatheter insertion of a stented aortic valve by the left ventricular apex. *Ann Thorac Surg* 2008;86:46-54.

26. Otten AM, van Domburg RT, van Gameren M, Kappetein P, Takkenberg JJM, Bogers AJJC, Serruys PW, de Jaegere P. Population characteristics, treatment assignment and survival of patients with aortic stenosis referred for percutaneous valve replacement. *EuroIntervention* 2008;4:250-5.

