Balloon valvuloplasty as destination therapy in elderly with severe aortic stenosis: a cardiac catheterization study

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Abstract

Background In the current era of transcatheter aortic valve replacement, there is renewed interest in balloon aortic valvuloplasty (BAV) and invasive hemodynamic evaluation of aortic stenosis (AS). The current report aimed to study the invasive hemodynamics of severe AS patients treated with BAV as destination therapy and to identify factors associated with better hemodynamic outcome and prognosis.

Methods From 2009 to 2012, 63 high risk elderly patients were treated with BAV as destination therapy for symptomatic severe AS and were all prospectively included in the study. Their hemodynamics were invasively evaluated during catheterization, pre- and post-BAV at the same session. All Post-BAV patients were regularly followed-up.

Results The patients (82 ± 6 years, 52% male) had post-BAV aortic valve area index (AVAi) significantly increased and mean pressure gradient (MPG) significantly reduced. During the follow-up of 0.9 (maximum 3.3) years, those with post-BAV AVAi < 0.6 cm²/m² compared with the AVAi ≥ 0.6 cm²/m² group had significantly higher mortality (60% vs 28%, log-rank P = 0.02), even after adjusting for age, gender, atrial fibrillation, chronic kidney disease, diabetes mellitus, coronary artery disease and EuroSCORE [HR: 5.58, 95% confidence interval (CI): 1.62–19.20, P = 0.006]. The only independent predictor of moderate AS post-BAV was the pre-BAV AVAi increase by 0.1cm²/m² (OR: 3.81, 95% CI: 1.33–10.89, P = 0.01). Pre-BAV AVAi ≥ 0.39 cm²/m² could predict with sensitivity 84% and specificity 70% the post-BAV hemodynamic outcome.

Conclusions BAV as destination therapy for severe AS offered immediate and significant hemodynamic improvement. The survival was significantly better when a moderate degree of AS was present.

Keywords: Balloon aortic valvuloplasty; Invasive hemodynamics; Outcome; Severe aortic stenosis; The elderly

1 Introduction

The generally accepted gold standard in the management of severe symptomatic aortic stenosis (AS) is surgical aortic valve replacement.[1] Transcatheter aortic valve replacement (TAVR) has emerged as a non-inferior choice for the high risk patients and the preferred method of management for those deemed inoperable.[2–4] Balloon aortic valvuloplasty (BAV), even though it has been proven to have significantly inferior long-term outcomes compared to TAVR,[3,5] may be the only option in patients with comorbidities and high risk scores that makes the TAVR a futile procedure or in inoperable patients with anatomy that precludes TAVR.[5–8] It has been revisited recently mainly as a bridge to TAVR or in a triage algorithm pre TAVR.[9–11]

In the current era of transcatheter AS treatment, the invasive hemodynamic assessment of AS severity has been re-generated.[12] Although the guidelines for the assessment of AS are based mainly on echocardiography,[1] an evaluation by catheterization has been suggested for the cases with discrepancies in clinical and echocardiographic data.[12,13] However, systematic data on the invasive hemodynamic evaluation of severe AS during catheterization pre- and post-BAV are scarce.

The current analysis aims to study the invasively obtained hemodynamic parameters of severe AS in patients treated with BAV as destination therapy and correlate them to the hemodynamic and long-term clinical outcome.

2 Methods

2.1 Study population

From April 2009 till November 2012, the data of all the
BAV procedures that were performed as destination therapy at AHEPA University Hospital, for symptomatic patients with severe AS who were considered of very high surgical risk or inoperable, were prospectively collected. The decision for BAV as destination therapy was made by a heart team, considering that the availability of TAVR was very limited for financial reasons, due to the Greek economic crisis.\(^{14}\) Severe AS was defined as an aortic valve area index < 0.6 cm\(^2\)/m\(^2\) according to the guidelines on the management of valvular heart diseases,\(^{11}\) and the high surgical risk assessment was based on the logistic Euroscore I and Euroscore II or an inoperable condition. All comorbidities, such as arterial hypertension, diabetes mellitus, renal dysfunction, coronary artery disease, atrial fibrillation and electrocardiographic conduction abnormalities had been prospectively collected. Chronic kidney disease was considered when the estimated creatinine clearance was < 45 mL/min,\(^{15}\) and coronary artery disease when angiographic lesions > 50% were present or revascularization had been performed. A 2-dimensional echocardiographic study was performed pre-BAV and post-BAV at discharge from the hospital.

### 2.2 BAV procedure

All the procedures were performed with local anesthesia through a transfemoral access, with a 10F or 12F sheaths depending on the size of the balloon and an initial bolus of Heparin 70 U/kg intravascularly. In all the cases, the valvuloplasty balloon was the Cristal balloon (BALT, Montmorency, France) and the available sizes were 20 mm, 23 mm and 25 mm with a length of 45 mm. The selection of the balloon size was based on aortography measurements of the corrected annulus in the left anterior oblique projection as described elsewhere;\(^{16}\) in brief, the maximum distance between the lower edge of the cusps in systole (uncorrected annulus diameter) was multiplied by the factor 1.154, assuming that what was measured was the side of a triangle inscribed in a circle and the final result was the diameter of the circle, i.e., the annulus. Irrespective of the estimated annulus diameter, the diameter of the balloon that was selected was at least 3 mm smaller than the diameter of the sinotubular junction. Balloon oversizing, for purposes of analysis, was defined as balloon diameter/uncorrected annulus diameter ratio > 1.085, which was the median value of the observed ratio.

During balloon inflation, rapid right ventricular pacing for a duration of 7–10 s, at 180 or 200 beats per minute was performed in order to stabilize the balloon across the valve. The manual balloon inflation with a 60 mL syringe, was considered effective when the recorded aortic pressure waveform during the inflation did not show any aortic pulse fluctuations suggestive of complete sealing of the orifice of the valve. If that was not achieved and the aortic pressure waveform was not suggestive of aortic regurgitation, a second inflation was performed. If the mean transaortic pressure gradient (MPG) was not reduced by 30%–40%, then a larger balloon was used, if that was considered safe, based on the relative size of the initial balloon.\(^{10}\) Haemostasis was performed by local vascular pressure, banding and bed rest. In the case of patients who were hemodynamically unstable in cardiogenic shock pre-BAV, the procedure was performed under inotropic or mechanical (intra-aortic balloon pump) support.

The procedure was not performed under transesophageal echocardiographic guidance because most of the patients were not under anaesthesia and intubated. As a result, there are no echocardiographic data during the procedure.

### 2.3 Cardiac catheterization data

The catheterization measurements and the whole procedure were frequently performed with the patient’s upper body on a wedge at 30 degrees elevation, with the transducer reference level at the mid chest at the fourth intercostal space. The left heart pressure measurements were performed with two catheters at the level of the aortic valve. The initial measurements, prior to the valvuloplasty, were performed under inotropic or mechanical (intra-aortic balloonoplasty) measurements. With an end-hole catheter in the left ventricle and a pigtail catheter in the ascending aorta and the post-valvuloplasty measurements with two pigtail catheters. The mean pressure gradient was calculated and the ejection time period was measured at the crossing points of the two pressure curves. The pulmonary wedge pressure was obtained with a Swan-Ganz catheter and the correct position was verified by comparing it to the simultaneous recording of the left ventricular diastolic pressure. The cardiac output and stroke volume were calculated by the Fick method using an estimated O\(_2\) consumption of 125 mL/min per m\(^2\) body surface area and oxygen saturation measurements from the pulmonary artery and aorta and the heart rate at the time of measurements.\(^{17,18}\) The aortic valve area (AVA) was computed by using the Gorlin formula and then indexed to body surface area (AVA\(_i\)).\(^{19}\) When post-BAV AVAi was ≥ 0.6 cm\(^2\)/m\(^2\) and MPG ≤ 40 mmHg the post-BAV grade of stenosis was considered moderate.\(^{1}\) The global left ventricular hemodynamic load was assessed by calculating the valvulo-arterial impedance as \(Z_v = \text{Left ventricular stroke volume index} \times \text{vascular load by calculating the systemic vascular resistance SVR} = \frac{[80 \times \text{mean aortic pressure}]}{\text{cardiac output}}\) and the systemic arte-
All measurements were performed immediately after the time of valve crossing pre-BAV and not earlier than 10 min post-valvuloplasty.

2.4 Complications and outcome

All the procedural complications and all complications during the hospitalization including blood transfusions were recorded. Aortic regurgitation was assessed pre- and post-procedure with angiography. Complete 12-lead electrocardiography was performed pre- and post-procedure and twice daily for the first 48 h and then daily. All the patients after their discharge were followed-up at the Heart Valve Outpatient Clinic and in between their visits by monthly phone calls. The end-point of the study was all-cause mortality and cardiac mortality (death due to pulmonary oedema, low cardiac output, sudden cardiac death). The study was approved by the ethical committee of the AHEPA University Hospital, Thessaloniki, Greece.

2.5 Statistical analysis

Continuous variables were expressed as mean ± SD and categorical variables as frequency (%). The continuous variables assessed pre-BAV versus post-BAV were compared by the paired Student-\(t\) test or the Mann-Whitney \(U\) test, as appropriate. Categorical variables were compared by the chi-square or the Fisher test, as appropriate.

The cumulative probability of survival was estimated by Kaplan-Meier curves. Survival of the two groups based on the hemodynamic outcome after BAV were compared by the log-rank test in an unadjusted manner. Multivariate Cox regression analysis was used to test the association between survival of the two groups and clinically relevant variables. The result was reported as hazard ratio (HR) and 95% confidence interval (CI).

Univariate binary logistic regression analysis was performed to test which parameters can predict the BAV hemodynamic outcome. In the multivariate model, all the variables with a univariate \(P < 0.1\) were inserted. The result was reported as odds ratio (OR) and 95% CI. Variables with a correlation coefficient > 0.7 were excluded to avoid collinearity. Receiver operating characteristic analysis was used to assess the value of pre AVAI in predicting the BAV hemodynamic outcome and was reported as area under the curve and 95% CI for sensitivity and specificity.

Statistical analysis was conducted with SPSS software version 20 (SPSS, Chicago, IL). A \(P\)-value < 0.05 was considered statistically significant.

3 Results

3.1 Baseline characteristics

The current study included 63 consecutive patients (mean age 82 ± 6 years, 52% male) who underwent 68 BAV procedures. Table 1 displays the demographic and clinical characteristics of this elderly and high surgical risk population. Noteworthy, all the patients were at New-York Heart Association (NYHA) functional class III (21%) and IV (79%) and 35 (56%) of them had multiple hospital admissions for heart failure, angina or syncope before BAV. The procedural BAV characteristics and the anatomical measurements on aortography are shown in Table 2.

### Table 1. Baseline patient characteristics (\(n = 63\)).

| Characteristic                  | Value   |
|--------------------------------|---------|
| Age, yr                        | 82 ± 6  |
| Males                          | 35 (56%)|
| Body mass index, kg/m²         | 27 ± 5  |
| Atrial fibrillation            | 33 (52%)|
| Chronic kidney disease         | 40 (63%)|
| Hypertension                   | 55 (87%)|
| Diabetes                       | 34 (54%)|
| Coronary artery disease        | 47 (75%)|
| Stroke                         | 11 (17%)|
| Logistic EuroSCORE I, %        | 36 ± 21 |
| EuroSCORE II, %                | 22 ± 20 |
| Cardiogenic shock              | 14 (22%)|
| NYHA class IV                  | 50 (79%)|
| NYHA class III                 | 13 (21%)|
| Angina CCS class IV            | 18 (29%)|
| Angina CCS class III           | 8 (13%) |
| Syncope                        | 16 (25%)|

Data are presented as mean ± SD or \(n\) (%) unless otherwise indicated. CCS: Canadian Cardiovascular Society; NYHA: New-York Heart Association.

### Table 2. Balloon aortic valvuloplasty characteristics (\(n = 68\)).

| Characteristic                  | Value   |
|--------------------------------|---------|
| Aortic annulus diameter, mm    | 22 ± 3  |
| Corrected aortic annulus diameter, mm | 26 ± 3 |
| Aortic sinuses diameter, mm    | 34 ± 4  |
| Aortic sinotubular junction diameter, mm | 29 ± 4 |
| Ascending aorta diameter, mm   | 35 ± 4  |
| Balloon diameter > 23 mm        | 28 (41) |
| Balloon/aortic annulus diameter, mm | 1.08 ± 0.13 |
| Balloon/corrected aortic annulus diameter, mm | 0.93 ± 0.11 |
| Concomitant PCI                 | 10 (15%)|
| Second time procedure           | 5 (7%)  |
| On inotropic support            | 10 (15%)|
| On mechanical support           | 4 (6%)  |

Data are presented as mean ± SD or \(n\) (%). PCI: percutaneous coronary intervention.
3.2 BAV clinical outcome

During the median follow-up of 0.9 years (interquartile range 0.2–1.6 years) with a maximum of 3.3 years, 38 deaths were recorded and 25 of them were of cardiac cause. During this period, 21 patients were hospitalized for cardiac symptoms and 16 had multiple re-admissions; three patients were hospitalized during the first month, 11 patients until the 6th month and until the 12th month 20 patients in total. Figure 1 presents the functional class improvement 1-month post BAV and the gradual deterioration thereafter; 62% were NYHA functional class I-II at 1-month, 46% at 6 months and 24% at 1 year follow-up. Noteworthy, six patients underwent successful non-cardiac surgical treatment post-BAV.

3.3 BAV hemodynamic outcome

Table 3 displays in detail all the invasively assessed hemodynamic changes that occurred after BAV. Post-BAV, the AVAi was significantly increased from 0.41 ± 0.13 cm²/m² to 0.55 ± 0.17 cm²/m², P < 0.001 and the MPG was significantly reduced from 46 ± 19 mmHg to 27 ± 11 mmHg, P < 0.001. It is noteworthy that post-BAV, 19 patients (30%) had AVAi ≥ 0.6cm²/m² and these all had MPG ≤ 40 mmHg, compatible with moderate AS.

According to the echocardiographic evaluation pre- vs. post-BAV at discharge, the AVAi was significantly increased (0.28 ± 0.09 cm²/m² vs. 0.40 ± 0.12 cm²/m², P < 0.001), the MPG was significantly reduced (50 ± 15 mmHg vs. 46 ± 19 mmHg, P < 0.001) and the left ventricular ejection fraction was significantly increased (46% ± 14% vs. 52% ± 14%, P < 0.001).

Figure 1. Functional class change post-BAV. Pre-BAV, 79% of the patients were in NYHA class IV. Post-BAV, the percent of patients in NYHA class I-II was 62% at the 1st month and declined to 46% at six months and to 24% at one year, while the percent of deaths was gradually increasing from 23% to 32% to 47%, respectively. BAV: balloon aortic valvuloplasty; NYHA: New-York Heart Association.

Table 3. Invasive hemodynamic assessment pre- and post-balloon aortic valvuloplasty.

|                         | Pre-BAV | Post-BAV | P-value |
|-------------------------|---------|----------|---------|
| AS severity             |         |          |         |
| AVAi, cm²               | 0.73 ± 0.25 | 0.98 ± 0.32 | < 0.001 |
| AVAi index, cm²/m²      | 0.41 ± 0.13 | 0.55 ± 0.17 | < 0.001 |
| Mean gradient, mmHg    | 46 ± 19  | 27 ± 11  | < 0.001 |
| Left ventricular function |          |          |         |
| Cardiac output, L/min   |         |          |         |
| Cardiac index, L/min per m² |       |          |         |
| SV index, mL/m²         | 35 ± 10  | 33 ± 10  | 0.01    |
| Ejection time, ms       | 299 ± 43 | 272 ± 37 | < 0.001 |
| Left ventricular afterload |       |          |         |
| Z va, mmHg/mL per m²    | 5.35 ± 1.92 | 5.13 ± 1.56 | 0.09    |
| SVR, mmHg.min/L         | 1501 ± 478 | 1584 ± 485 | 0.04    |
| SAC, mL/mmHg per m²     | 0.51 ± 0.16 | 0.45 ± 0.14 | < 0.001 |
| Left Ventricular pressures |       |          |         |
| Systolic pressure, mmHg | 189 ± 33 | 168 ± 24 | < 0.001 |
| End-diastolic, mmHg     | 22 ± 8   | 21 ± 11  | 0.41    |
| Mid-diastolic, mmHg     | 14 ± 7   | 14 ± 7   | 0.16    |
| Ascending aorta pressures |       |          |         |
| Systolic pressure, mmHg | 129 ± 21 | 136 ± 23 | 0.001   |
| Diastolic pressure, mmHg| 57 ± 14  | 57 ± 12  | 0.87    |
| Mean pressure, mmHg     | 84 ± 13  | 87 ± 14  | 0.02    |
| Pulmonary artery pressures |       |          |         |
| Systolic pressure, mmHg | 50 ± 17  | 44 ± 14  | < 0.001 |
| Diastolic pressure, mmHg| 19 ± 8   | 17 ± 7   | 0.008   |
| Mean pressure, mmHg     | 31 ± 12  | 27 ± 9   | 0.001   |
| Heart rate, beats per minute | 78 ± 17 | 79 ± 17 | 0.41    |

Data are presented as mean ± SD. AVA: aortic valve area; AS: aortic stenosis; BAV: balloon aortic valvuloplasty; SAC: systemic arterial compliance; SV: stroke volume; SVR: systemic vascular resistance; Z va: valvulo-arterial impedance.

3.4 Procedural complications based on BAV hemodynamic outcome

The post-BAV group with AVAi ≥ 0.6 cm²/m² had comparable procedural complications to the post-BAV group with AVAi < 0.6 cm²/m², 8 (42%) vs. 19 (43%) respectively: 1 (5%) stroke occurred versus no stroke (P = 0.13), aortic regurgitation was increased in 5 (26%) versus 9 (21%) (P = 0.64), and transient conduction abnormalities were found in 2 (10%) versus 10 (23%) (P = 0.24), with no need for permanent pacemaker insertion.

3.5 Mortality based on BAV hemodynamic outcome

The post-BAV AVAi < 0.6 cm²/m² group compared to the AVAi ≥ 0.6 cm²/m² group had significantly higher
all-cause mortality (60% vs. 28%, log rank $P = 0.02$) (Figure 2A) and cardiac mortality (42% vs. 17%, log rank $P = 0.04$) (Figure 2B). Even after adjusting for age, gender, atrial fibrillation, chronic kidney disease, diabetes mellitus, coronary artery disease and logistic EuroSCORE I, the AVAi < 0.6 cm$^2$/m$^2$ group had significantly higher all-cause mortality (HR: 5.58, 95% CI: 1.62–19.20, $P = 0.006$) (Figure 2C) and cardiac mortality (HR: 8.31, 95% CI: 1.54–44.88, $P = 0.01$) (Figure 2D) compared with the AVAi ≥ 0.6 cm$^2$/m$^2$ group.

3.6 Predictors of BAV hemodynamic outcome

Clinically, invasive hemodynamic and catheterization procedural parameters that could be predictive of the hemodynamic outcome post-BAV are presented in Table 4. After multivariate analysis, the only independent predictor of moderate AS after BAV was the pre-BAV AVAi increase by 0.1 cm$^2$/m$^2$ (OR: 3.81, 95% CI: 1.33–10.89, $P = 0.01$). Pre-BAV AVAi ≥ 0.39 cm$^2$/m$^2$ could predict the post-BAV hemodynamic outcome of moderate AS with sensitivity 84% and specificity 70% (area under the curve: 0.83, 95% CI: 0.71–0.94, $P < 0.001$) (Figure 3).

4 Discussion

The current study reported that BAV in patients with severe AS offered an immediate improvement of the hemodynamics, as evaluated by cardiac catheterization during the procedure. This analysis confirmed that BAV as a destination therapy is associated with poor survival in the case AVAi < 0.6 cm$^2$/m$^2$ post-BAV. Nonetheless, when moderate AS was accomplished after BAV, the survival was significantly longer. Patients with pre-BAV AVAi ≥ 0.39 cm$^2$/m$^2$ were more likely to end with moderate stenosis immediately after BAV.
Table 4. Univariate and multivariate predictors of moderate aortic stenosis post balloon aortic valvuloplasty.

| Clinical variables | Univariate analysis | Multivariate analysis |
|--------------------|---------------------|----------------------|
| OR  | 95% CI | P-value | OR | 95% CI | P-value |
| Age, yr | 0.91 | 0.81–1.02 | 0.11 | 3.81 | 1.33–10.89 | 0.01 |
| Male gender | 1.49 | 0.49–4.52 | 0.48 | — | — | — |
| Hypertension | 2.58 | 0.51–13.11 | 0.25 | — | — | — |
| Diabetes | 0.78 | 0.27–2.31 | 0.66 | — | — | — |
| Chronic kidney disease | 0.99 | 0.33–2.96 | 0.98 | — | — | — |

Invasive hemodynamic variables pre-BAV

| AVA index 0.1cm²/m² increase | 3.65 | 1.74–7.63 | 0.001 | 3.81 | 1.33–10.89 | 0.01 |
| MPG, mmHg | 0.94 | 0.90–0.98 | 0.004 | — | — | — |
| SV index, mL/m² | 1.05 | 0.99–1.12 | 0.07 | — | — | — |
| Zva, mmHg/mL per m² | 0.54 | 0.34–0.85 | 0.009 | 1.10 | 0.44–2.74 | 0.84 |
| SVR, mmHg.min/L | 1.00 | 1.00–1.01 | 0.04 | 1.00 | 0.99–1.01 | 0.60 |
| SAC 0.1 mL/mmHg per m² increase | 1.42 | 1.00–2.02 | 0.05 | 0.86 | 0.42–1.77 | 0.69 |

Catheterization procedure variables

| Balloon D, cm | 1.01 | 0.72–1.44 | 0.93 | — | — | — |
| Balloon/aortic annulus D | 0.02 | 0.01–3.64 | 0.14 | — | — | — |
| Balloon/corrected annulus D | 0.09 | 0.01–4.44 | 0.14 | — | — | — |
| Balloon oversizing | 0.50 | 0.16–1.58 | 0.24 | — | — | — |
| Concomitant PCI | 3.39 | 0.80–14.47 | 0.11 | — | — | — |
| Inotropes or IABP | 0.96 | 0.22–4.22 | 0.96 | — | — | — |

*MPG was not included in the multivariate due to close collinearity to AVAi pre-BAV (correlation coefficient 0.77); †SV index was not included in the multivariate due to close collinearity to Zva pre-BAV (correlation coefficient 0.72). AVA: aortic valve area; BAV: balloon aortic valvuloplasty; D: diameter; IABP: intra-aortic balloon pump; MPG: mean pressure gradient; PCI: percutaneous coronary intervention; SAC: systemic arterial compliance; SV: stroke volume; SVR: systemic vascular resistance; Zva: valvulo-arterial impedance.

Figure 3. ROC curve analysis for pre-BAV AVAi as a predictor of post-BAV moderate aortic stenosis. Pre-BAV AVAi ≥ 0.39 cm²/m² predicts moderate aortic stenosis post-BAV with sensitivity of 84% and specificity 70%. AVAi: aortic valve area index; AUC: area under the curve; BAV: balloon aortic valvuloplasty; ROC: receiver operating characteristic.

4.1 BAV impact on hemodynamics

According to large registries (National Heart Lung and Blood Institute Balloon Valvuloplasty Registry and Mansfield Registry) for the BAV effect in the early 1990’s, BAV significantly improves the AVA and MPG acutely.[21,22] Even the most recent studies in the 2010 report, an acute increase in the AVA and reduction of the MPG were reported pre and post-BAV.[5,6,10] In line with these studies, the current one reported significant immediate improvement in AVA and MPG. Almost one third of patients post-BAV had AVAi ≥ 0.6 cm²/m², which is lower in comparison to the values previously reported,[10] but in current study those patients had as well MPG < 40 mmHg, and thus they could be considered as classical moderate stenosis. The stroke volume index was significantly reduced, which can be explained by the reduction in the left ventricular ejection time from 299 ± 43 ms to 272 ± 37 ms (P < 0.001), due to aortic valve stenosis improvement and reduction of the afterload. However, the cardiac output and cardiac index were not reduced immediately post-BAV. The systolic, diastolic and median pulmonary artery pressures were significantly re-
duced as previously described. However, diastolic pulmo-

nary artery pressure failed to represent the diastolic left
ventricular pressure which is known to happen in patients
with left ventricular systolic dysfunction (ejection fraction
46% ± 14% in current report) due to a wave in pulmonary

waveforms.

4.2 BAV outcome

Although the BAV technique over time has been im-

proved by reducing the balloon catheter diameter, so as a
10-F sheath can be used in reducing the vascular complica-
tions, and by applying rapid right ventricular pacing, so as
the balloon positioning is more stable and accurate, the sur-
vival after stand-alone BAV has not been increased. The sur-

vival after BAV in the early 1990's was about 55% at one
year,[10,24] and recently has been reported to range
from 50% to 67% at one year.[5,6,10,25] Ben-Dor, et al.[10] re-
ported that the survival after BAV at a median of 0.5 years
follow-up was significantly better when final AVA was > 1

cm² versus AVA < 1 cm² (63.6% vs. 42.1%, P < 0.001). The

current study confirms and expands this knowledge; when

moderate stenosis (AVAi ≥ 0.6 cm²/m² and MPG ≥ 40

mmHg) was achieved, post-BAV the survival was signifi-
cantly increased to 75% at a median follow-up of 0.9 years.

Noteworthy, moderate stenosis post-BAV was achieved
without paying the price of more complications.

4.3 Predictors of outcome

The predictors of mortality after BAV have been well
described; clinical parameters such as poor NYHA func-
tional status, renal failure, coronary artery disease, urgent
procedure, hemodynamic parameters such as cardiogenic
shock, poor left ventricular systolic function, high pulmo-

nary artery pressures, and technical parameters such as
number of balloon inflations have been suggested to predict

survival after BAV.[5,6,10,25–27] However, the predictors of

moderate stenosis post-BAV have not been previously de-
scribed. The current study suggests that pre-BAV AVAi ≥

0.39 cm²/m² may predict a moderate stenosis post-BAV in
elderly patients. Hence, for those patients BAV may be

considered as destination therapy in terms of prognosis,
whenever TAVR cannot be an option. Balloon oversizing

seems not to offer a better hemodynamic outcome, while

increasing the potential complications, like new ventricu-

lar conduction disturbance, as previously reported.[28–30]

4.4 Limitations

The main limitation of this prospective study was the li-

mited number of patients treated with BAV. However, the

number of patients who are currently treated with BAV as
destination therapy worldwide is restricted. It has to be ac-

knowledged that the clinical practice to offer BAV as desti-
nation therapy might sound suboptimum according to the
current guidelines. This was solely dictated by the current
financial limitations in Greece that have impacted signifi-
cantly on healthcare provisions. However, a cohort of

elderly, very high surgical risk patients treated with BAV as
destination therapy was analyzed in an attempt to optimize a
very strict patient selection for TAVR, whenever the costly
therapy of TAVR is not an available option.

4.5 Conclusions

BAV as a destination therapy for high surgical risk eld-

erly patients with severe AS, whenever TAVR was not avail-
able, offered immediate and significant improvement in the
hemodynamics as assessed in the catheterization laboratory.
The survival was significantly better when a moderate de-
gree of AS had been achieved post-BAV. Pre-BAV AVAi ≥
0.39 cm²/m², could satisfactorily predict the accomplish-
ment of moderate AS after the procedure.

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