



Survival Rate of High-Risk Elderly Patients with Severe Aortic Stenosis Treated with Perfusion-Balloon Valvuloplasty without Rapid Pacing: A Comparison with the Italian National Institute of Statistics (ISTAT)

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Abstract

Aim: Percutaneous Balloon Aortic Valvuloplasty (BAV) is actually recommended as a bridge to surgery or transcatheter aortic valve replacement in patients with severe Aortic Stenosis (AS) in particular clinical settings. In this study, we compared the two years mortality of 50 patients (mean age 86.8 ± 4.68 years) with symptomatic AS undergoing BAV which does not require rapid ventricular pacing, with the mortality tables provided from the Italian National Institute of Statistics (ISTAT) in a period between 2019 and 2021.

Methods and Results: At a median of 25 months, 36% patients died. The median time between BAV and mortality was 11 months. The independent predictors of mortality were the NYHA class at admission and STS score. ($p < 0.01$ for both). From the comparison between the percentages of our data and the prospective probability of survival calculated by ISTAT for the whole population of the Marche region and whole Italian territory the survival rates were higher in the population undergoing BAV than in the control population for the age groups of 85 to 89 and 90 to 94.

Conclusion: Our data showed a higher long-term survival rate for the symptomatic patients with severe AS treated with BAV, in comparison with the prospective probability of survival calculated by ISTAT in the 2019, 2020 and 2021 for the age groups of 85 to 89 and 90 to 94 both in the Marche region and the whole Italian territory. Our encouraging results should be confirmed from larger future study.

Introduction

Aortic Stenosis (AS) represents the most common primary valve disease leading to surgery or catheter intervention in Europe and North America, with an increasing prevalence due to the aging population [1]. Transcatheter Aortic Valve Replacement (TAVR) has been shown to be superior in terms of mortality to medical therapy in extreme-risk patients and non-inferior or superior to surgery in high-risk patients [2,3]. The percutaneous Balloon Aortic Valvuloplasty (BAV) is actually recommended by the European Society of Cardiology Guidelines as a bridge to surgery or TAVR or as a diagnostic means in patients with severe AS and particular clinical settings [3-9].

We have acquired a good experience using a non-occlusive balloon for BAV (True Flow balloon; BD/Bard) which does not require Rapid Ventricular Pacing (RVP), in symptomatic elderly patients with severe AS.

In our recent study we have reported, for the first time, that perfusion-balloon valvuloplasty without RVP performed in a center without on-site cardiothoracic surgical support is a safe and valid option in elderly patients with severe AS at one year of follow-up [10].

In this new single center study, we provided the survival rate at two years of a high-risk

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elderly patient’s population with symptomatic AS treated with BAV and compared these data with the tables provided from the Italian National Institute of Statistics (ISTAT) [11].

Materials and Methods

From 2018 to 2021, a total of 50 patients with a clinical manifestation of heart failure due to severe AS, were treated with BAV and were all prospectively included in the study. The Society of Thoracic Surgeons (STS) risk score was adopted to assess the cardiac mortality risk [12]. We used True Flow perfusion-balloon valvuloplasty for aortic valve stenosis without RVP.

All procedures were completed without RVP. Hemodynamic parameters were invasively evaluated during catheterization, before and immediately after BAV, at the same session.

All device-related safety events were evaluated (device-related death, stroke, annulus rupture, coronary occlusion, or ventricular perforation during the dilation procedure). Vascular complications related to device insertion in the femoral-iliac axis were also investigated. All patients were regularly followed in order to detect the rate of mortality.

Data distribution was assessed according to the Kolmogorov-Smirnov test. Continuous variables were compared using an unpaired Student’s t test or Mann-Whitney U test, as appropriate, and data were expressed as mean ± standard deviation or as median (range). Categorical data were evaluated using the Chi-squared test. Event-free survival was measured from the date of the procedure to the occurrence of death. The cumulative incidence of death was estimated using Kaplan-Meier method. Independent predictors of survival were analyzed using Cox proportional-hazards regression model. The results are reported as adjusted Odds Ratio (OR) with associated 95% Confidence Interval (CI). A 2-tailed P-value <0.05 was established as the level of statistical significance for all tests. SPSS statistical software, version 17.0 (SPSS Italia, Inc) was used for analyses.

Our data have been compared with ISTAT mortality tables for 2019, 2020 and 2021. Considering the origin of the patients undergoing BAV, the tables for the Italian territory and the Marche region were used [11]. For the comparison, three age groups were considered: 80 to 84 years, 85 to 89 years and 90 to 94 years. The percentage of survival and the ratio between the living patients and the total number of patients were calculated for each age group.

Results and Discussion

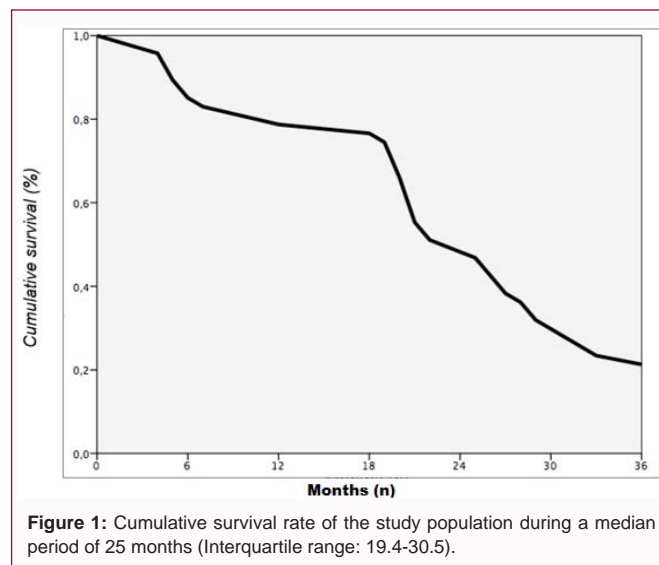
Clinical characteristics of the 50 patients and procedural features are reported in Table 1

Mean patient age was 87.0 ± 3.9 years, 30% were males, and median STS score was 10% (range: 9 to 19.0). All patients were admitted to our center for heart failure; 32 were classified as New York Heart Association (NYHA) class III (64%) and 18 as NYHA class IV (36%). BAV represented destination therapy in 45 patients (90%) and as bridge to TAVR in 5 patients (10%). The median ejection fraction evaluated by echocardiogram was 55% (range, 39 to 55), with a median trans-aortic pressure gradient of 48 mmHg (range, 38 to 55). In the catheterization laboratory, the peak Left Ventricular (LV) to aortic pressure gradient significantly decreased from 60 mmHg (Interquartile Range [IQR], 45 to 70) to 26 mmHg (IQR, 18 to 30) immediately after balloon inflation (P<0.001).

Table 1: Clinical characteristics and procedural features.

Variables	(n=30)
Age, years, mean ± SD	87.56 ± 4.10
Male, n (%)	7 (23)
CAD, n (%)	9 (30)
Anemia, n (%)	20 (66)
Peripheral disease, n (%)	9 (30)
Renal failure, n (%)	3 (10)
Destination therapy, n (%)	27 (90)
LVEF, %, median (IQ)	55 (40-56)
PLV to AP gradient before BAV, mmHg, median (IQ)	55 (48.7-66.2)
PLV to AP gradient after BAV, mmHg, median (IQ)	26 (15.7-30)
% decrease after BAV, median (IQ)	56 (36-04)
Procedural time, min, median (IQ)	88 (50-185)
Death, n (%)	12 (40)
Death from BAV, months, median (IQ)	11 (1-22)
Follow-up, months, median (IQ)	12 (1-33)

AP: Aortic Pressure; BAV: Balloon Aortic Valvuloplasty; BMI: Body Mass Index, CAD: Coronary Artery Disease; IQ: Interquartile Range; LVEF: Left Ventricular Ejection Fraction; PLV: Peak Left Ventricular; SD: Standard Deviation; STS score: Society of Thoracic Surgeons risk score



There were no reports of device-related safety events. During the procedure, only a single vascular complication occurred: A common femoral dissection with a transient hypotension that did not require the use of inotropes and was successfully treated by covered stenting. During recovery, 2 deaths were reported (1 at 3 days due to acute renal insufficiency and 1 at 1 week due to pneumonia).

At a median of 25 months (IQR, 19 to 33), 18 patients (36%) died (Figure 1). The median time between BAV and mortality was 11 months (IQR, 3.5 to 19).

At univariate analysis, independent predictors of mortality were the NYHA class at admission (OR, 3.13; 95% CI, 2.90 to 3.28; P<0.001), and STS score (OR, 4.4; 95% CI, 1.74-7.20; P=0.002). At multivariate analysis, these results remained confirmed (P<0.01 for both).

From the comparison between the percentages of our data and the

Table 2: Comparison of survival rates between study population and Italian National Institute of Statistics data.

Study population					ISTAT data					
					Italy Survival rate, %			Marche region Survival rate, %		
Age class	Alive (n)	Death (n)	Total (n)	Survival rate, %	2019 (%)	2020 (%)	2021 (%)	2019 (%)	2020 (%)	2021 (%)
80-84	8	4	12	63.6	69.4	65.8	67.6	71.1	67.9	68.6
85-89	15	8	23	63.6	49.8	45.2	47.7	49.9	46.9	46.3
90-94	9	6	15	57.1	29.7	25.1	28.3	29.5	24.9	26.6

prospective probability of survival calculated by ISTAT in the 2019, 2020 and 2021 for the whole population of the Marche Region, the survival rates were higher in the population undergoing BAV than in the control population for the age groups of 85 to 89 (63% vs. 49%, 46% and 46%, respectively) and 90-94 (57% vs. 29%, 24% and 26%, respectively). On the contrary, in the 80 to 84 years age group, the survival percentage of our data was slightly lower in comparison with the prospective probability of survival provided by ISTAT during the three years considered (62% vs. 71%, 67% and 68%, respectively) (Table 2).

Considering the data from the whole Italian territory, the survival rates were higher in the population undergoing BAV than in the control population for the age groups of 85 to 89 (63% vs. 49%, 45% and 47%, respectively) and 90-94 (57% vs. 29%, 25% and 28%, respectively) during the three considered years. For the 80 to 84 years age group, the survival percentage of our data was slightly lower in comparison with the prospective probability of survival provided by ISTAT during the three years (63% vs. 69%, 65% and 67%, respectively) (Table 2).

This study reported that: (1) non-occlusive balloon for BAV, which does not require RVP, represents an useful and safe procedure in elderly patients with severe AS and clinical presentation of heart failure (NYHA \geq III) at 2 years follow-up; (2) the NYHA class at admission and STS score are the only independent predictors of mortality; (3) there is a higher long-term survival rate in this class of patients in comparison with the prospective probability of survival calculated by ISTAT in the 2019, 2020 and 2021 for the age groups of 85 to 89 and 90 to 94 both in the Marche Region and in the whole Italian territory.

In the last years, there has been an increase in the average age of hospitalized patients, with multiple comorbidities that contraindicate the common interventions envisaged by the guidelines [1,2].

In this context, BAV could represent an option also as destination therapy in patients older than 85 with symptomatic AS, ensuring an improving survival in comparison with a sample of the same years old.

Nonetheless, this type of approach does not prevent that these patients, once treated with BAV for symptomatic heart failure in a hospital without on-site surgery, could be subsequently referred to a center where they can undergo TAVI.

Our data could also suggest a particular attention for patients with high STS and advanced degree of heart failure, in order to attempt an improvement of their outcome.

Conclusion

Our data showed a higher long-term survival rate for a population of high-risk elderly patients with symptomatic AS treated with BAV,

in comparison with the prospective probability of survival calculated by ISTAT in the 2019, 2020 and 2021 for the age groups of 85 to 89 and 90 to 94 both in the Marche region and in the whole Italian territory. Our preliminary and encouraging data need to be confirmed by future larger studies.

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