Clinical Investigation

Contemporary Use of Balloon Aortic Valvuloplasty

in the Era of Transcatheter Aortic Valve Implantation

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The development of transcatheter aortic valve implantation (TAVI) has increased the use of balloon aortic valvuloplasty (BAV) in treating aortic stenosis. We evaluated our use of BAV in an academic tertiary referral center with a developing TAVI program.

We reviewed 69 consecutive stand-alone BAV procedures that were performed in 62 patients (mean age, 77 ± 10 yr; 62% men; baseline mean New York Heart Association functional class, 3 ± 1) from January 2009 through December 2012. Enrollment for the CoreValve® clinical trial began in January 2011. We divided the study cohort into 2 distinct periods, defined as pre-TAVI (2009–2010) and TAVI (2011–2012). We reviewed clinical, hemodynamic, and follow-up data, calculating each BAV procedure as a separate case.

Stand-alone BAV use increased 145% from the pre-TAVI period to the TAVI period. The mean aortic gradient reduction was 13 ± 10 mmHg. Patients were successfully bridged as intended to cardiac or noncardiac surgery in 100% of instances and to TAVI in 60%. Five patients stabilized with BAV subsequently underwent surgical aortic valve replacement with no operative deaths. The overall in-hospital mortality rate (17.4%) was highest in emergent patients (61%).

The implementation of a TAVI program was associated with a significant change in BAV volumes and indications. Balloon aortic valvuloplasty can successfully bridge patients to surgery or TAVI, although least successfully in patients nearer death. As TAVI expands to more centers and higher-risk patient groups, BAV might become integral to collaborative treatment decisions by surgeons and interventional cardiologists. ***(Tex Heart Inst J 2014;41(5):469-76)***

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Percutaneous balloon aortic valvuloplasty (BAV) was proposed in 1986 by Alain Cribier as an alternative to surgical aortic valve replacement (SAVR) for treating symptomatic aortic stenosis in high-risk patients.[1] Poor long-term results in comparison with SAVR relegated BAV to American College of Cardiology/American Heart Association class IIB indications in patients who are thought to be inoperable.[2] The transcatheter aortic valve implantation (TAVI) technique uses BAV as an essential procedural step to evaluate annular size, to evaluate displacement of the aortic valve leaflets adjacent to the left main coronary artery, and to facilitate delivering and placing the percutaneous valve.[3] We hypothesized that the introduction of a TAVI program to a cardiac center would influence BAV procedural volumes and indications, not only through its use as an adjunctive step in TAVI, but also in evaluating the severity of aortic stenosis—offering an improvement in left ventricular (LV) dysfunction and thus potentially bridging inoperable patients to TAVI. The purpose of this study was to examine the changing volumes and indications for BAV in a tertiary referral center with a newly developed TAVI program, and to examine the outcomes of patients who had undergone BAV.

Patients and Methods

Using current procedural terminology (CPT) billing codes, we identified consecutive patients who had undergone BAV from January 2009 through December 2012 at our academic tertiary referral center. Comorbidity, clinical, hemodynamic, procedural, and follow-up data were obtained from reviews of hospital records. Data on deaths were obtained from Social Security Death Index records. Study approval was obtained from our institutional review board.

Definitions

Inclusion criteria included all stand-alone BAV procedures for aortic stenosis from January 2009 through December 2012. Cases in which BAV was used only during TAVI procedures were excluded. To evaluate the impact of the TAVI program on BAV use, we divided the study cohort into 2 distinct time periods: the pre-TAVI period (2009–2010) and the TAVI period (2011–2012). These time periods were chosen because the CoreValve® (Medtronic, Inc.; Minneapolis, Minn) randomized clinical trial began enrollment at our center in January 2011. The collected data included patients' age, sex, medical and surgical history, and current comorbidities. To evaluate whether end-organ function affected outcome, we quantified liver dysfunction by using the Model for End-Stage Liver Disease (MELD) score; we quantified renal dysfunction by using data on creatinine clearance. A EuroSCORE II and a Society of Thoracic Surgeons (STS) score was calculated for each patient. Presenting symptoms and clinical conditions were reviewed in order to classify patients as follows: 1) emergent: presenting with recent or ongoing cardiogenic shock or decompensated heart failure due to aortic stenosis; 2) palliation: elective BAV in patients deemed to be nonsurgical candidates; 3) bridge to cardiac surgery: patients in whom it was judged that LV systolic function recovery (and thus operability) might be achieved via BAV; and 4) bridge to noncardiac surgery: patients in whom urgent noncardiac surgery was indicated but was thought to be prohibitive because of untreated aortic stenosis.

During the study period, 62 patients underwent 69 stand-alone BAV procedures (Table I). The mean age of the patients was 77.1 ± 10.24 years (range, 47–93 yr); mean New York Heart Association (NYHA) functional class, 3 ± 1; mean EuroSCORE II, 17.1 ± 19.2; and mean MELD score, 13 ± 7. Because these characteristics might have differed for the same patient at the time of a repeated BAV, we considered each BAV procedure to be a separate case and used a denominator of 69 to calculate percentages. The chief comorbidities were diabetes mellitus (in 43%), concomitant coronary artery disease (30%), and chronic obstructive pulmonary disease (22%). The indications for stand-alone BAV were palliation in 23 instances (33.3%), emergent in 18 (26.1%), bridge to noncardiac surgery in 15 (21.7%), bridge to TAVI in 10 (14.5%), and bridge to cardiac surgery in 3 (4.3%).

Pre- and postprocedural M-mode, 2-dimensional conventional, and Doppler echocardiography was performed; aortic valve area was calculated by means of the continuity equation. Transaortic valve gradients were derived from catheter pressure measurements during BAV. Retrograde femoral access via a percutaneous approach was used in all cases; the femoral arterial sheaths ranged from 9F to 14F in size. The preclose technique was used after the placement of a 6F Perclose® sheath (Abbott Vascular, part of Abbott Laboratories; Redwood City, Calif).[4] Heparin was administered at a dose of 70 U/kg. Rapid ventricular pacing at a rate of 180 to 200 beats/min was achieved with use of temporary balloon-tipped pacing wires. Balloon size depended upon the echocardiographically measured annular size. The number of balloon inflations was at the discretion of the operator.

Procedural death was defined as death caused by complications of the BAV. During the follow-up period, echocardiography was performed at the discretion of the clinician. Length of postprocedural stay was defined as the number of days from BAV to the time of discharge from the hospital. When patients underwent subsequent noncardiac surgery during the index hospitalization, length of stay was defined as the number of days between BAV and the noncardiac operation.

TABLE I. Baseline Characteristics of the 62 Patients at the Time of the 69 Balloon Aortic Valvuloplasty Procedures

Variable	Value
Age, yr (range)	77.1 ± 10.24 (43–79)
Male	43 (62)
NYHA functional class	3 ± 1
EuroSCORE II	17.1 ± 19.2
Left ventricular ejection fraction	0.48 ± 0.19
Left ventricular ejection fraction <0.30	7 (10)
Diabetes mellitus	30 (43)
Chronic obstructive pulmonary disease	15 (22)
End-stage renal disease	10 (14)
Prior cerebrovascular accident	5 (7)
Peripheral vascular disease	11 (16)
Concomitant coronary artery disease	21 (30)
Prior Surgery	
Cardiac	21 (30)
CABG	19 (28)
Mitral valve replacement	1 (1)
CABG and mitral valve replacement	1 (1)
Myocardial infarction within 90 d	8 (12)
MELD score	13 ± 7

CABG = coronary artery bypass grafting; MELD = Model for End-Stage Liver Disease; NYHA = New York Heart Association

Values are expressed as mean ± SD or as number and percentage, unless otherwise stated.

Statistical Analysis

Analyses were performed with use of SPSS Statistics for Windows, version 20.0 (IBM Corporation; Armonk, NY). Univariate analysis was performed by means of the Mann-Whitney U test for continuous variables and

the χ^2 test for categorical variables, with significance at $P < 0.05$. Survival analysis was performed by means of the Kaplan-Meier method. Continuous values are reported as mean ± SD, and categorical data are reported as number and percentage.

Results

During the pre-TAVI period, 18 patients underwent 20 stand-alone BAV procedures; and during the TAVI period, 44 patients underwent 49 stand-alone BAV procedures (Fig. 1). Figure 2 shows the substantial change between periods in the indications for stand-alone BAV. During the pre-TAVI period, BAV was performed almost entirely as palliation or as a bridge to noncardiac surgery. In contrast, during the TAVI period, there was a marked increase in the use of BAV in emergent patients and a slight increase in its use for palliation.

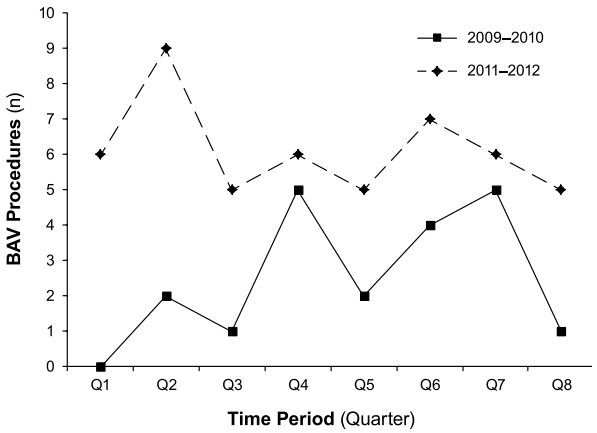

Fig. 1 *Graph shows the number of balloon aortic valvuloplasty (BAV) procedures by quarter (Q).*

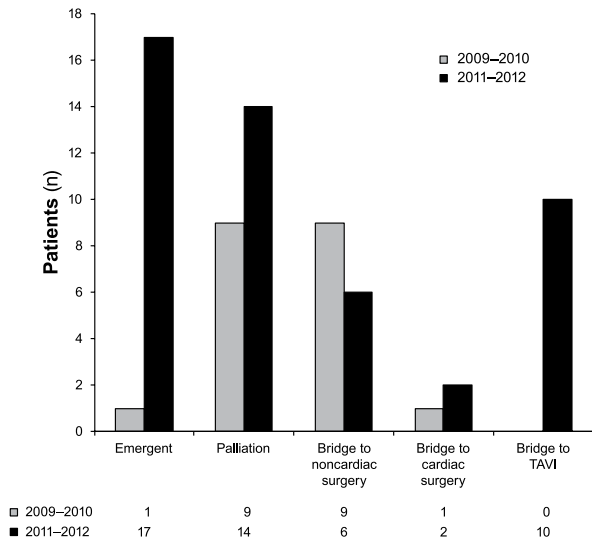

Fig. 2 *Chart shows a comparison of indications for balloon aortic valvuloplasty before and during the transcatheter aortic valve implantation (TAVI) periods.*

Table II shows baseline characteristics and several significant differences between patients in the pre-TAVI and TAVI time periods. In comparison with pre-TAVI patients, patients treated during the TAVI period had a significantly higher mean EuroSCORE II (19.9 ± 19.6 vs 10.2 ± 16.7; $P=0.0003$), NYHA functional class (3.2 ± 0.9 vs 2.3 ± 1; $P=0.0003$), STS score (14.9 ± 14.5 vs 8.3 ± 9; $P=0.04$), and pulmonary artery systolic pressure (51 ± 15 vs 37 ± 13 mmHg; $P=0.001$). There were no significant differences in mean age, LV ejection fraction, aortic valve area, or aortic valve gradient.

Procedural Data

For the entire cohort, the mean catheter-derived transaortic valve gradient at baseline was 40.1 ± 17.5 mmHg. The mean reduction in gradient was 13.4 ± 10.2 mmHg, for a final mean gradient of 27.2 ± 12 mmHg. Mean aortic valve area, measured echocardiographically by means of the continuity equation, was 0.69 ± 0.22 cm^2 preprocedurally and 0.84 ± 0.27 cm^2 postprocedurally, at a mean duration of 17 ± 54 days. The mean balloon size was 20.9 ± 2 mm. Hemodynamic support (such as with an LV assist device or an intra-aortic balloon pump) was used in 8 procedures (11.6%). Concomitant percutaneous coronary intervention was performed in 17 instances (24.6%). Between the periods, there were no significant differences in balloon size, changes in aortic valve area, or changes in mean gradient.

Outcomes

There were no intraprocedural deaths in the entire cohort. One vascular access site complication, involving femoral arterial bleeding, was controlled by means of manual compression. There were no periprocedural strokes. The mean length of stay was 3.9 ± 4.1 days. The overall in-hospital mortality rate was 17.4% (n=12) and was highest in emergent patients (61.1%, n=11). The mortality rate among palliation patients was 4.3% (n=1): one palliation patient died of an ischemic bowel. Among patients bridged to cardiac or noncardiac surgery, none died.

All patients who underwent BAV as a bridge to cardiac or noncardiac surgery were successfully bridged to their intended procedures. An additional 5 patients underwent SAVR (Fig. 3). Of the patients intended for bridging to TAVI, 60% subsequently underwent that procedure (n=6). The univariate analysis of emergent survivors versus nonsurvivors revealed a significant difference in preoperative MELD scores (9.4 ± 2.6 vs 16.5 ± 8.2; $P=0.02$); there were no other differences in baseline, procedural, or postprocedural characteristics (Table III).

At a mean follow-up duration of 21 ± 12 months (range, 3–45 mo), the mortality rate among the 18

TABLE II. Characteristics of the Study Cohort by Time Period

Variable	Pre-TAVI Procedures (2009–2010) n=20	TAVI Procedures (2011–2012) n=49	*P* Value
Age (yr)	74 ± 9.6	78.3 ± 9.6	0.145
Male	9 (45)	34 (69)	0.06
Body mass index (kg/m^2)	26 ± 5	26 ± 6	0.9
Diabetes mellitus	7 (35)	23 (47)	0.36
Coronary artery disease	5 (25)	16 (33)	0.53
Myocardial infarction within 90 d	3 (15)	5 (10)	0.57
Concomitant mitral disease (>moderate)	6 (30)	22 (45)	0.25
Prior cardiac surgery	3 (15)	18 (37)	0.08
Chronic obstructive pulmonary disease	6 (30)	9 (18)	0.38
Peripheral vascular disease	4 (20)	7 (14)	0.56
History of CVA or TIA	1 (5)	4 (8)	0.65
Creatinine clearance (mL/min)	62 ± 31	52 ± 27	0.22
End-stage renal disease	2 (10)	8 (16)	0.5
Preoperative hematocrit (%)	35.6 ± 5.7	33.7 ± 5.1	0.18
Pulmonary artery systolic pressure (mmHg)	37 ± 13	51 ± 15	0.001
Preoperative MELD score	10 ± 5	13 ± 7	0.12
NYHA functional class	2.3 ± 1	3.2 ± 0.9	0.003
EuroSCORE II	10.2 ± 16.7	19.9 ± 19.6	0.003
Society of Thoracic Surgeons score	8.3 ± 9	14.9 ± 14.5	0.04
Baseline mean aortic valve gradient (mmHg)	35.1 ± 15.4	42.2 ± 18.1	0.11
Left ventricular ejection fraction	0.49 ± 0.17	0.47 ± 0.2	0.7
Aortic valve area (cm^2)	0.7 ± 0.3	0.7 ± 0.2	0.33

CVA = cerebrovascular accident; MELD = Model for End-Stage Liver Disease; NYHA = New York Heart Association; TAVI = transcatheter aortic valve implantation; TIA = transient ischemic attack

Values are expressed as mean ± SD or as number and percentage. *P* <0.05 was considered statistically significant.

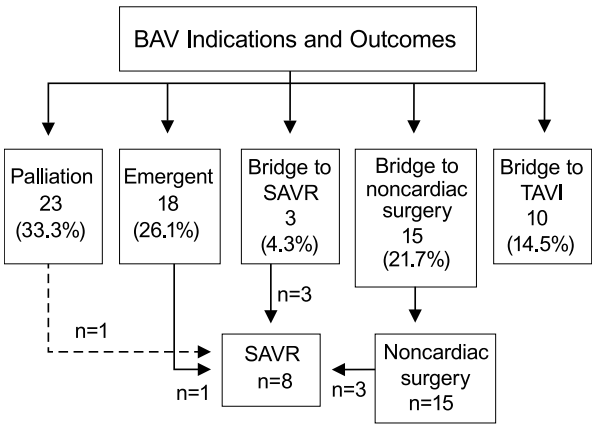

Fig. 3 *Chart shows indications and outcomes of balloon aortic valvuloplasty (BAV). Data are presented as number and percentage.*

SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation

emergent patients was 66.7% (n=12) and 52.2% among the 23 palliative patients (n=12); 1,397 days (45 mo) was the longest survival duration in the cohort (Fig. 4). Of the 7 emergent patients who survived to be discharged from the hospital, one died while awaiting evaluation for CoreValve trial enrollment. Two patients underwent repeat BAV, and one of them subsequently underwent TAVI. One patient had an annular size too large for the CoreValve and subsequently underwent SAVR and coronary artery bypass grafting. One patient refused further treatment and was discharged to hospice care. Two patients were lost to clinical follow-up.

Of the 22 palliation patients who survived to be discharged from the hospital, 11 died during the follow-up period. Reasons for excluding these patients from CoreValve trial enrollment included the comorbid conditions of dementia, mitral regurgitation, cirrhosis, and malignancy. Of the 6 patients who were to be bridged to TAVI, 4 did not undergo TAVI during the follow-up

TABLE III. Characteristics of Emergent Survivors versus Nonsurvivors

Variable	Survivors (n=7)	Nonsurvivors (n=11)	*P* Value
Preoperative Characteristics			
Age (yr)	83.3 ± 7.3	78.2 ± 8.5	0.15
Creatinine (mg/dL)	1.19 ± 0.3	2.28 ± 1.6	0.25
Creatinine clearance (mL/min)	51 ± 18	43 ± 21	0.3
Hematocrit (%)	34.5 ± 5.4	30.1 ± 2.5	0.09
Albumin (g/dL)	3.1 ± 0.6	3.1 ± 0.7	1
MELD score	9.4 ± 2.6	16.5 ± 8.2	0.02
PASP (mmHg)	49.6 ± 11.9	55.1 ± 8.2	0.54
LV ejection fraction	0.34 ± 0.22	0.40 ± 0.25	0.7
Severe mitral regurgitation	0	4	0.09
Mean gradient (mmHg)	43.6 ± 20.4	46.5 ± 22.5	0.79
Aortic valve area (cm^2)	0.7 ± 2.2	0.6 ± 0.1	0.3
EuroSCORE II	48.9 ± 16.6	37.0 ± 20.7	0.21
Society of Thoracic Surgeons score	24.8 ± 14.1	30.1 ± 17.5	0.48
Procedural Characteristics			
Delta decrease in mean AV gradient (mmHg)	12.5 ± 6.9	16.3 ± 14.6	0.76
Final mean AV gradient (mmHg)	30.1 ± 14.5	30.3 ± 10.3	0.76
Balloon size (mm)	21 ± 1.9	22 ± 2.4	0.39
Postprocedural Characteristics			
Delta rise in creatinine (mg/dL)	0.03 ± 0.24	0.16 ± 1.93	0.38
Delta decrease in hematocrit (%)	5.9 ± 3.7	2.1 ± 2.6	0.35
Final aortic valve area (cm^2)	0.73 ± 0.2	0.86 ± 0.3	0.76

AV = aortic valve; LV = left ventricular; MELD = Model for End-Stage Liver Disease; PASP = pulmonary artery systolic pressure

Values are expressed as mean ± SD or as number. *P* <0.05 was considered statistically significant.

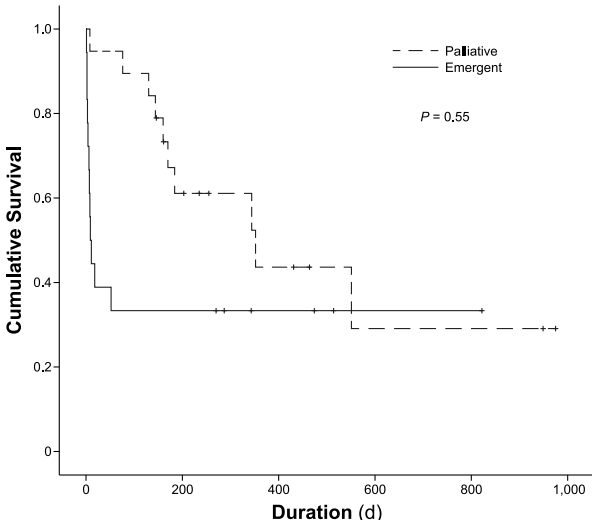

Fig. 4 *Graph shows a survival comparison of emergent and palliative patients (P=0.55 for log-rank comparison).* P *<0.05 was considered statistically significant.*

period: 2 had aortic valve gradients lower than those required for trial inclusion, one had a cerebrovascular accident while waiting for TAVI, and one was still awaiting TAVI.

Discussion

The introduction of TAVI has brought a distinct population of patients—historically thought to be candidates only for medical therapy—into consideration for invasive therapies such as BAV. The reasons for this are many but are in part related to improvements in BAV techniques; later series have yielded better results than those in the initial registries.[5,6] In the PARTNER trial, BAV was part of standard medical therapy in 84% of the non-TAVI patients.[7] Other reported uses for BAV are palliation[8-10] and bridging to TAVI.[11] As was reported in other series,[12] we found that implementing a TAVI program increased BAV volumes. In addition, the profile of patients considered for BAV markedly changed: 94% of

the patients who presented emergently did so during the TAVI period, during which patients had significantly higher EuroSCORE II, STS, and NYHA-class scores but similar hemodynamic measurements (LV ejection fraction, aortic valve area, and mean transaortic gradient). The higher in-hospital mortality rate was driven by the larger number of emergent patients.

The increasing use of BAV in the era of TAVI raises some challenging questions. What is the current state of BAV use? Which patients should be selected? Table IV[11-15] shows a multivariate analysis of factors that predicted mortality rates in 2 large studies[12,13] and one small study[14] from Europe (where TAVI use, and presumably BAV use, are more extensive), and in one large study from the United States.[11] No single factor was common to all studies; however, reduced LV ejection fraction, NYHA class, and shock or emergent status were found to be significant in 3 of the 4 studies. The 30-day mortality rate ranged from 13% to 15%. The long-term mortality rate ranged from 33% to 36% at one year, and it was as high as 50% at 6 months in one series.

A small study by Tissot and colleagues[15] differed from the above studies in its findings. A higher percentage of patients presented in cardiogenic shock (29%); however, the 30-day mortality rate was similar, at 15%. Furthermore, 56% of patients were bridged to TAVI and 9.8% to SAVR. No late deaths occurred in those who presented in cardiogenic shock and survived to be discharged from the hospital. This was similar to our emergent-patient population, in which only one late death occurred.

As TAVI develops and becomes more widely available, decisions regarding extremely high-risk patients will become a challenge as technological limitations diminish. Investigators have repeatedly shown that long-term outcomes in BAV patients bridged to TAVI or SAVR are superior to outcomes in palliative use alone.[10,11,13,16] In a study of patients referred for TAVI screening,[16] those who were successfully bridged to TAVI or SAVR had survival rates equivalent to those who had undergone primary TAVI or SAVR; without further interventions, the survival rate was equivalent to that of medical therapy alone. The authors noted that patients treated with stand-alone BAV had baseline characteristics similar to those of patients treated with bridge BAV, and that the differences related mainly to "qualitative, subtle parameters . . . which could hardly be quantified and reflected by the predictive risk scores."[16] Thus, the role of BAV as a "bridge to decision" for patients presenting in cardiogenic shock or decompensated heart failure continues to have value, with the caveat that the currently available scoring systems are insufficient to predict short-term survival rates. In fact, multiple investigators have shown that the current scoring systems have inadequate calibration and discriminatory power for predicting TAVI-related death.[17-19] Until new scoring systems are developed and validated, clinical response to BAV might also have value as a prognostic indicator of TAVI mortality rates, through measures of change in LV function or improvement in heart failure status. Some form of objective stratification is needed, because many studies have shown a failure of patients to progress to definitive therapy.[14] In 2012, the authors of an editorial urged transcatheter valve practitioners to "better define the relative role for TAVR [transcatheter aortic valve replacement] in extreme-risk patients as compared to the role of palliative BAV in patients who are unlikely

TABLE IV. Studies Mentioning Mortality Rates or Factors Predicting Death

Reference	Study Period	No. Pts.	Pts. Presenting in Shock (%)	Mortality Rate (%)	Factors Predicting Death	Bridge Procedures (%)	
						TAVI	SAVR
Ben-Dor I, et al.[11] (2010)	2000–2009	301	9	1.6 (in-hospital) 50 (181 d)	NYHA class IV, baseline renal failure, pulmonary systolic pressure, hematocrit drop, and BAV not as a bridge to TAVI or SAVR	4.9	5.7
Tissot CM, et al.[15] (2011)	2006–2009	41	29	15 (30 d)	Not studied	56	9.8
Daly MJ, et al.[14] (2012)	2008–2010	64	14	13 (30 d)	NYHA class >II, SBP <90 mmHg, LVEF <0.45, PG <80 mmHg, and eGFR <45 mL/min	7.8	4.7
Saia F, et al.[12] (2013)	2000–2010	415	5.5	5.1 (in-hospital) 33.2 (1 yr) 57.4 (2 yr)	LVEF, NYHA class IV, and shock	30.8	11.4
Khawaja MZ, et al.[13] (2013)	2003–2010	423	12.8	13.8 (30 d) 36.3 (12 mo)	Coexisting CAD, poor LV function, and urgent/emergent indication	18.2	7

BAV = balloon aortic valvuloplasty; CAD = coronary artery disease; eGFR = estimated glomerular filtration rate; LV = left ventricular; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PG = peak aortic gradient; Pts = patients; SAVR = surgical aortic valve replacement; SBP = systolic blood pressure; TAVI = transcatheter aortic valve implantation

to gain a survival benefit despite successful TAVR due to other life-threatening comorbid conditions."[20]

An unexpected finding in our study was the number of patients who eventually underwent SAVR despite having been considered nonsurgical candidates initially, and the 100% operative survival rate. Similarly, Saia and colleagues[16] reported that BAV referrals resulted in a 28% increase in referrals to SAVR, with no in-hospital deaths in the patients who proceeded to surgery. This suggests that referrals for TAVI and BAV are capturing patients who previously would not have been referred for cardiac surgery because of the perceived risk.

We have found that BAV has a valuable role in the complex treatment algorithm of patients who have symptomatic aortic stenosis, and that BAV yields acceptable long-term results. The procedure might also be used as a compromise measure in patients who have active infections that preclude prosthetic valve implantation, or in patients with acute renal failure. We found that BAV is valuable as palliative therapy, similar to its role in other contemporary series. Given the strict criteria for inclusion in clinical trials, some patients now undergoing BAV for palliation might later be eligible for commercially available percutaneous valves. This would be expected to decrease the volume of BAV procedures as stand-alone therapy. Nevertheless, for the foreseeable future, a subset of patients will not be candidates for TAVI, because of anatomic issues such as annular size, coronary artery anatomy, or peripheral vascular disease. In addition, the cost-effectiveness of TAVI relative to BAV is undetermined in patients who have a shorter life expectancy because of comorbidities such as malignancy.

Limitations of the Study

Limitations of this study include its retrospective nature, the limits of the applicability of data from a single academic tertiary center, the restrictive criteria of a clinical trial in offering patients the option of TAVI, and the lack of data on fragility. Our single-center population and experience were influenced by local practice and referral patterns, possibly explaining the difference in variables that predict mortality rates. Follow-up echocardiography was performed at the discretion of the treating clinicians, rather than routinely; therefore, comparisons of hemodynamic data might be of limited value. Furthermore, the increased use of BAV in emergent patients may not have been a consequence of referral patterns, but rather of greater willingness on the part of the treating physicians. Nevertheless, the outcome remains the same, and the results are instructive.

Conclusion

In conclusion, this study captures the real-world experience of a single center during a distinct period of development and implementation of a TAVI program. The use of BAV has undergone a resurgence in the TAVI era, with changing patterns and indications for use. As TAVI develops and is used more widely, the use of stand-alone BAV is expected to diminish, but it might retain a role in the complex treatment algorithm for patients who have severe aortic stenosis. Although further studies are needed to determine the role of BAV in risk stratification or triage, the procedure should be considered a tool in the arsenal of cardiologists and cardiac surgeons, particularly during a team approach.

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