Emerging Practice Patterns and Outcomes of Percutaneous Aortic Balloon Valvuloplasty in Patients With Severe Aortic Stenosis

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A total of 33 patients with severe aortic stenosis undergoing percutaneous aortic balloon valvuloplasty (PABV) for bridging or palliative therapy were reviewed; the emerging treatment patterns for this procedure are described. Longitudinal data suggest that PABV provides a significant reduction in peak and mean aortic valve gradients with > 12-month survival for more than half of observed patients. This supports the current application of PABV, which is currently limited to palliative care and bridging therapy to more definitive forms of future treatment, including transcatheter aortic valve implantation.

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Key words: Aortic balloon valvuloplasty • Transcatheter aortic valve implantation • Aortic stenosis • Survival

Percutaneous aortic balloon valvuloplasty (PABV) is an accepted modality for the management of severe calcific aortic stenosis (AS) in symptomatic elderly patients who are deemed inoperable.[1] Unfortunately, PABV has poor long term-results; the 3-year mortality rate for patients > 75 years is roughly 80%.[2] Based on these data, PABV has largely fallen out of favor as a definitive treatment option. Elderly patients with AS demonstrate a poor response to medical management alone as well, with an average survival of 2 to 3 years.[1] Therefore, the definitive treatment of severe AS in this patient population remains surgical aortic valve replacement (AVR).[3-8]

Case Series Review

After obtaining approval from the Institutional Review Board, we reviewed the records of 33 patients who underwent PABV for severe degenerative AS at the Providence Heart Institute, Providence Hospital and Medical Center (Southfield, MI) from 1990 through 2009. The indication for PABV in the majority of these patients was hemodynamic instability and anticipation of AVR with clinical improvement after PABV procedure. Prior to PABV each patient was evaluated by a cardiologist and a thoracic surgeon and was deemed not a surgical candidate for AVR without prior PABV. All patients underwent pre-PABV coronary angiography and if significant coronary artery obstruction was discovered it was corrected via angioplasty or stenting. Patients were then hemodynamically stabilized after revascularization and prior to PABV. If hemodynamic stability was not achieved in a timely manner, and AS was considered a significant contributing factor, then those patients underwent urgent PABV despite being hemodynamically unstable.

Each patient was individually assessed using the EuroSCORE calculation[9,10] based on risk factors for operative mortality with cardiac surgery. Individual patient EuroSCOREs and baseline characteristics are listed in Table 1. A total of 24 of the 33 patients (86%) had greater than three major comorbid diseases (Table 2). All of our patients were > 74 years with a mean age of 83.5 years. The overall mean EuroSCORE was 10, which is associated with a 15% chance of operative mortality. The all-cause mortality rate of our patients is markedly similar to what has been previously reported in large post-PABV registries[11-15] (Table 2). A pre- and post-PABV two-dimensional echocardiogram was performed on each patient and used to measure corresponding aortic valve gradients (Table 1). An example of a patient with planimetry of the aortic valve by echocardiography at baseline, maximal balloon inflation as seen on cineangiography, and postdilatation planimetry are shown in Figures 1, 2, and 3, respectively. Using intraprocedural hemodynamic variables pre- and post-PABV peak aortic valve gradients were recorded and are illustrated in Figure 4. The Gorlin equation was used to measure pre- and post-PABV aortic valve areas. The mean aortic valve area measured 0.59 cm^2 before PABV and 0.90 cm^2 after PABV. Post-PABV survival duration was derived by subtracting the date of death reported by the Social Security Death Index from the date of the procedure (Table 1). The longest observed survival post-PABV was seen in two patients who both eventually underwent AVR and

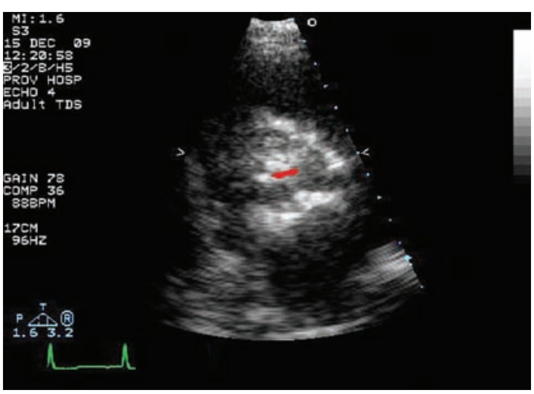


Figure 1. *A prepercutaneous aortic balloon valvuloplasty echocardiographic short axis view of a severely stenotic aortic valve in systole, with the valve opening shaded in* red.

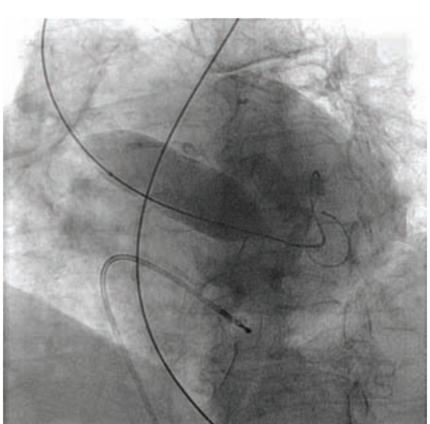


Figure 2. *The same patient undergoing percutaneous aortic balloon valvuloplasty; the cineangiographic image displays a Mansfield balloon at maximum inflation traversing the aortic valve with a temporary pacing wire placed in the right ventricle.*

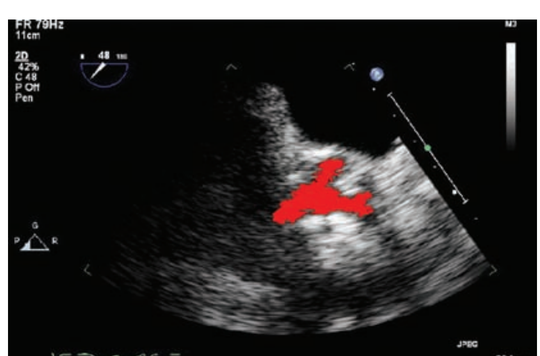


Figure 3. *A postpercutaneous aortic balloon valvuloplasty short-axis view of the same patient depicting a significantly larger valve opening that is again shaded in* red.

Table 1
Individual Characteristics, Hemodynamic Data, and Survival Duration

Age (Y)	Sex	EF (%)	Creatanine (mg/dL)	EuroSCORE	Pre-PABV Mean Gradient	Post-PABV Mean Gradient	Pre-PABV Peak Gradient	Post-PABV Peak Gradient	Deceased	Duration (Mo)
91	F	65	0.5	10	44	32	69	53	No	36[a]
82	F	70	2.3	11	45	30	64	59	No	28[a]
84	F	70	0.9	9	64	59	87	86	No	24[a]
93	F	65	0.6	11	44	32	62	41	No	15[a]
77[b]	M	30	5.3	10	38	36	63	48	No	14[a]
82	F	70	2	11	64	28	89	36	No	14[a]
74	F	60	0.6	7	54	27	88	35	No	12[a]
86	F	35	0.6	10	58	28	104	49	Yes	88
79	F	50	1.2	8	50	30	75	55	Yes	50
81	M	25	0.9	10	72	26	121	43	Yes	39
84	F	55	1.2	9	61	36	85	43	Yes	38
90	F	40	1.2	12	61	34	80	42	Yes	38
88	M	40	1.6	10	78	53	94	83	Yes	36
86	M	20	1.1	12	29	16	51	35	Yes	25
75	M	45	1.2	11	45	31	75	38	Yes	21
78	M	50	1.9	8	57	12	84	26	Yes	19
87	M	60	1.5	11	80	25	91	40	Yes	17
76	M	60	3.3	12	60	48	102	78	Yes	15
88	F	40	1.3	11	46	27	86	36	Yes	12
87	F	40	1	10	74	44	112	82	Yes	11
85	F	25	1.4	13	50	13	80	27	Yes	8
89	M	70	1.2	10	48	47	85	62	Yes	8
87	M	45	1.4	10	30	25	80	60	Yes	7
82[b]	M	20	4.3	12	29	19	35	24	Yes	7
86	M	55	2.8	9	23	12	37	25	Yes	3
88	M	60	2.4	10	61	52	100	90	Yes	2
81	F	45	1.8	10	43	29	62	32	Yes	2
82	F	55	0.8	11	53	38	70	42	Yes	2
74	F	30	1.6	11	25	12	45	23	Yes	< 1
86	F	35	1.8	12	42	21	67	39	Yes	< 1
76	F	65	1.6	11	40	39	60	55	Yes	< 1
85[c]	F	30	0.9	9	32	19	48	38	Yes	< 1
87[c]	M	25	1.9	14	29	4	56	7	Yes	< 1
83.5		47%	1.6	10	49 mm Hg	30 mm Hg	76 mm Hg	46 mm Hg		

Patients are listed according to duration of survival after PABV, from longest to shortest survival time. Creatinine values reported are same-day preprocedure measurements. Mean and peak gradients are echocardiographically derived. The final row represents the mean value of its respective column.

[a]Those currently living.

[b]Dialysis dependent.

[c]Patient died < 24 hours after PABV.

EF, ejection fraction; PABV, percutaneous aortic balloon valvuloplasty.

survived for more than 4 years (Table 1). Despite not having a standardized method for assessing improvement in functional capacity most patients stated they felt better after PABV.

Discussion

Pathophysiology of AS

Calcific degenerative aortic valvular stenosis is the most common cause of AS in persons > age 70 and is associated with extensive leaflet calcification and varying degrees of cusp rigidity.[16] Even though calcification is documented in > 90% of cases, studies have shown that when elderly

Table 2
Hemodynamic Results and Mortality From Published Registries and Our Case Series

	Registry Data	Case Series
Baseline mean valve area (cm^2)	0.53	0.59
Post-PABV mean valve area (cm^2)	0.86	0.90
Baseline peak gradient (mm Hg)	72	76
Post-PABV peak gradient (mm Hg)	39	46
Baseline mean gradient (mm Hg)	57	49
Post-PABV mean gradient (mm Hg)	30	30
3-year mortality rate (%)	77	79
2-year mortality rate (%)	65	70
12-month mortality rate (%)	45	45
6-month mortality rate (%)	15	27
≤ 30-day mortality rate (%)	14	15
In-hospital mortality rate (%)	10	6
≥ 2 major comorbid diseases[a] (%)		88
≥ 3 major comorbid diseases[a] (%)		73
≥ 4 major comorbid diseases[a] (%)		42

Cumulative data from four previous registries totaling 1554 patients. Valve areas and gradients are echocardiographic measurements.

[a]Hypertension, coronary artery disease, chronic kidney disease, chronic obstructive pulmonary disease, and diabetes mellitus.

PABV, percutaneous aortic balloon valvuloplasty.

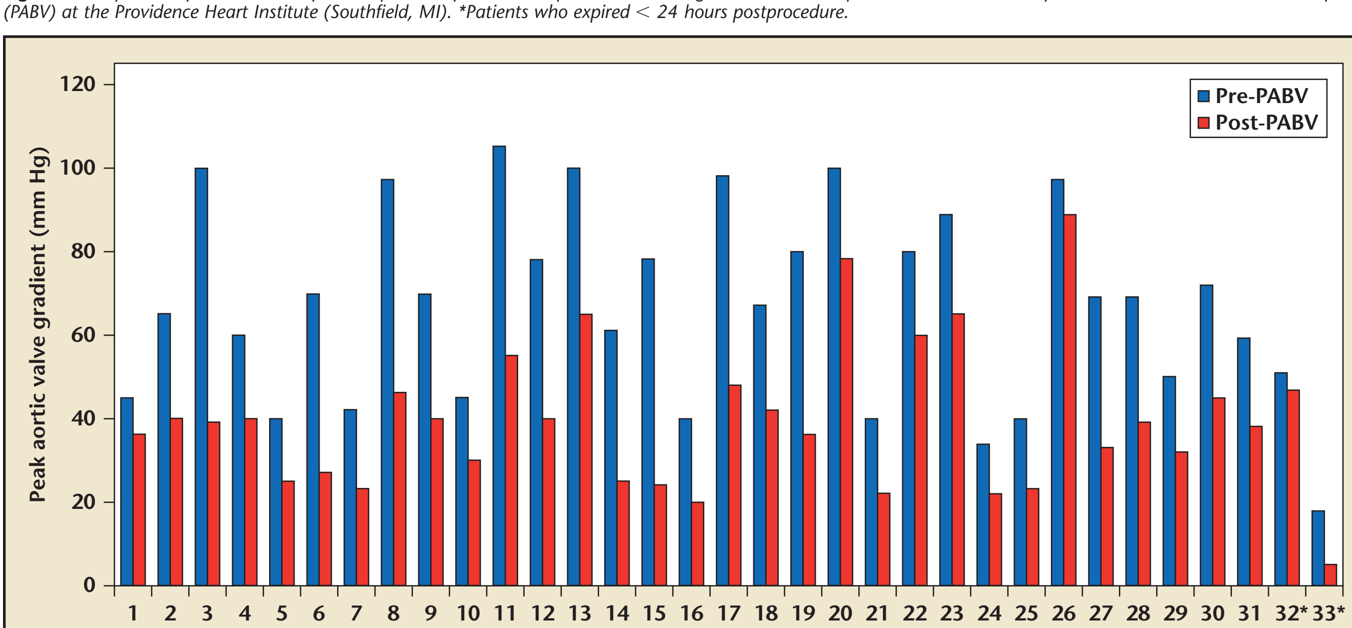
Data from Otto CM et al,[11] National Center for Health Statistics,[12] O'Neill WW,[13] Safian RD et al,[14] and Letac B et al.[15]

patients are compared with younger matched control patients, the elderly fare much worse after PABV.[17]

Patients who require PABV are frequently very ill with severe comorbid diseases and are not surgical candidates. The predicted operative mortality in our patient population was exceedingly high (> 15%), making surgery at least initially a prohibitive option. Managing severe degenerative calcific AS in the elderly using PABV has poor long-term outcomes primarily due to two factors: the pathology of degenerative AS and the multiple comorbidities seen in many elderly patients with AS.[2]

The traditional risk factors and the underlying pathology leading to aortic sclerosis and subsequent stenosis share similarities to, yet are distinctly different from atherosclerotic coronary artery disease.[18] Although calcific AS and coronary atherosclerosis have common risk factors, including older age, dyslipidemia, hypertension, and smoking, the pathogenesis of valvular disease appears to be more

Figure 4. *Graphical depiction of intraoperative pre- and postinflation peak aortic valve gradients of all 33 patients who underwent percutaneous aortic balloon valvuloplasty (PABV) at the Providence Heart Institute (Southfield, MI). *Patients who expired < 24 hours postprocedure.*



dependent on hemodynamic changes and less on lipid deposition. Turbulent, nonlaminar flow appears to stimulate myofibroblasts and pericytes in aortic valve leaflets to undergo osteoblastic transformation and begin the deposition of hydroxyapatite crystals. Randomized trials have confirmed that lowering low-density lipoprotein cholesterol does not influence the rate of calcification in coronary arteries, nor does it influence the rate of progression of AS.[19] Furthermore, the growing mass of calcium deposits on the aortic side of the valve leaflet restricts opening, causing more turbulence and accelerated calcification. Thus, statins have a beneficial impact on coronary atherosclerosis by delipidating plaques without a similar benefit at the level of the aortic valve.

PABV Outcomes According to the Etiology of AS

Response to PABV is determined by the etiology of the fixed left ventricular outflow obstruction. Congenital AS, which is derived from a different etiology than degenerative AS, responds differently to PABV. Lababidi and colleagues[20] first performed PABV in 1982 on children with congenital AS with successful results that were enough to make it a preferable option to open surgical valvotomy. Until the 1980s, severe AS was managed exclusively by surgical intervention. In 1985, Cribier and associates[21] performed the first PABV procedure on an adult with severe AS and had modest success.

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In the late 1980s, the four largest registries (hereafter referred to as *registry data*) evaluated 1554 elderly patients who underwent PABV for severe AS and reported 3-year outcomes, hemodynamic profiles, and restenosis and mortality rates.[11-15] Mean patient age was 76.5 years, average postvalvuloplasty mean gradient was 30 mm Hg (peak gradient, 39 mm Hg), and final valve areas ranged from 0.8 to 0.9 cm^2. Reported mortality rates were as follows: procedural, 0% to 5%; in-hospital, 4% to 10%; 1-year, 36% to 45%; 2-year, 65%; and 3-year, 77%. Even though most patients enjoyed immediate symptomatic improvement, 6-month restenosis rates were significantly high, approaching 80%.

The compilation of data regarding PABV attests to the fact that PABV does not alter the natural progression of degenerative AS.

Comparing our PABV data with existing literature we note similar results with respect to all outcome parameters measured: postinflation mean/peak gradients, postinflation aortic valve area, and survival rates. Specifically, overall 3-year mortality rates were nearly identical (Table 2).

The current goal for mean pressure aortic valve gradient after PABV is ≤ 30 mm Hg, and this was achieved in the majority of our patients. However, our post-PABV aortic valve areas were rarely > 1.0 cm^2, and the aortic valve areas in all cases progressively decreased at a rate of 0.1 to 0.3 cm^2 per year as described in the literature.[1] Because PABV cannot generate an orifice > 1.5 cm^2, the inherent effect of restenosis and return of significant gradients will always be expected. Repeat PABV should be considered in patients who remain nonsurgical candidates because it provides a median survival rate of approximately 3 years and maintains clinical improvement.[22]

The compilation of data regarding PABV attests to the fact that PABV does not alter the natural progression of degenerative AS. Our case review of 33 high-risk elderly patients with severe degenerative calcific AS who underwent PABV corresponds with previous literature results with respect to postinflation hemodynamics and mortality rates. This further adds to the data illustrating marginal effectiveness of PABV to improve long-term survival when used to treat patients with this progressive disease.

Currently, PABV is indicated as bridging therapy to eventual AVR in hemodynamically unstable patients, patients requiring high-risk percutaneous intervention, and as palliative therapy in patients with severe comorbid diseases.[23-25] Previously, there had been a general decline in utilizing PABV; however, development of transcatheter aortic valve implantation (TAVI) has led to a resurgence of interest in the PABV technique.[26] The emergence of TAVI

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has potentially realized a new role for PABV—bridging-to-percutaneous transcatheter intervention. Based on clinical studies a PABV preparatory procedure is commonly required prior to TAVI.[27]

TAVI has proven itself as a viable alternative to open heart surgery for patients who cannot undergo AVR and has even been shown to be more beneficial than AVR in select patients.[28-35] Due to the minimally invasive nature of TAVI, it significantly reduces perioperative morbidity and mortality in high-risk AS patients.[36] Using TAVI has exhibited immediate favorable hemodynamic results with respect to increasing the left ventricular ejection fraction (LVEF) and decreasing the mean aortic transvalvular gradient of patients with reduced LVEF when compared with AVR.[35,36] The Placement of AoRTic TraNscathetER Valve (PARTNER) trial, a recently concluded multicenter prospective randomized clinical trial pitting TAVI against standard medical therapy has yielded data suggesting TAVI should be the new standard of care for patients with AS who are deemed inoperable.[37] Interestingly, approximately 80% of the patients enrolled in the standard therapy arm of the study underwent PABV. These data suggest a trend toward PABV now being used as part of standard therapy.

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Thirty-one of our patients, all patients in the registry data, and 80% of patients in the standard therapy arm of the PARTNER trial were all managed medically post-PABV, spanning nearly 2 decades of interventional cardiology. Two-thirds of our patients and all the patients in the registry data received treatment prior to 2007, whereas all corresponding patients from the PARTNER trial were treated between 2007 and 2009. We believe this could be a contributing factor to the higher overall 30-day mortality rate seen in our series and the registry data when compared with the corresponding patients of the PARTNER trial. Our 30-day mortality rate and that of the registry data were 14% and 15%, respectively, which was significantly higher than the 2.8% published by the PARTNER trial investigators. However, this differential in mortality is lost at 12 months: 45% in both our series and the registry data and 50% in the PARTNER trial.

Clearly there is a progression toward improved short-term survival as medical care of the elderly and experience with PABV advances. Given these observations, interventional cardiologists could consider PABV an important component of standard therapy in patients with severe AS who cannot undergo AVR or TAVI. Advancements in cardiovascular care over the past 2 decades particularly in the area of geriatric medicine have allowed for PABV to become integrated with medical management to provide longer symptom-free survival for patients who cannot undergo AVR or TAVI.

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However promising, TAVI is not without its own inherent complications; documented complications include embolization or migration of the prosthetic valve, failure to cross the valve for the preceding PABV, cardiac tamponade, stroke, and iatrogenic arrhythmias/blocks necessitating permanent pacing.[38] A preliminary guideline has been developed detailing the need to gather data for post-TAVI complications and associated morbidity.[39] A recent observational study has documented post-TAVI conduction abnormalities and their effect on LVEF.[40] The investigators report that two-thirds of their patients who had TAVI experienced some type of conduction delay that resulted in a decreased LVEF from baseline, whereas patients who did not experience any conduction abnormalities had an increase in LVEF. For TAVI to achieve its full potential as a viable alternative to AVR, experienced endovascular physicians with training in cardiovascular medicine and PABV technique are needed at the forefront of this remarkable technology, which should decrease future morbidity and mortality rates attributed to severe AS.

Our review has all the limitations of a small case series concerning very ill patients in difficult treatment scenarios; we did not collect data regarding postdischarge echocardiograms and follow-up laboratory blood testing. Therefore, we do not have information regarding changes in mitral regurgitation and aortic restenosis rates after PABV and how they would have impacted patient symptoms. Also, without postdischarge laboratory values we were unable to trend certain parameters, such as a patient's renal function. Furthermore, we did not have a standardized patient status collection instrument at the time these patients underwent treatment, so we cannot make inferences regarding symptomatic responses in a quantifiable manner.

Conclusions

Our review of 33 patients who underwent PABV is consistent with existing registry data and supports published literature regarding PABV as a temporizing procedure for the management of severe degenerative AS in the elderly. We document similar outcomes to large registries with respect to hemodynamic results, restenosis rates, and overall mortality. As the elderly population swells and advances in medicine are improving longevity, PABV along the treatment pathway to TAVI or potentially AVR in severely ill patients with critical AS appears safe, reasonable, and associated with low 30-day mortality. ■

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Main Points

- Since its introduction more than 25 years ago, percutaneous aortic balloon valvuloplasty (PABV) has primarily been used as a bridging tool to eventual aortic valve replacement (AVR) in hemodynamically unstable patients and for palliative care purposes. However, with current developments in transcatheter aortic valve implantation (TAVI), PABV is enjoying a resurgence in popularity among interventional cardiologists and thoracic surgeons alike.
- TAVI has been the driving force behind the rising interest in PABV technique and prospective randomized clinical trials studying TAVI are using PABV as "standard medical therapy" and define its use as a prerequisite for patients electing to undergo TAVI.
- With a rapidly growing body of evidence, TAVI is proving itself as a viable and even superior alternative to surgical AVR in select patient populations, and with continued advancements in medical therapy and technology it may even someday supersede surgical AVR as treatment of choice for aortic stenosis.

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