Balloon Aortic Valvuloplasty

Current indications and use in unique clinical settings.

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In large series, balloon aortic valvuloplasty (BAV) has demonstrated restenosis rates of 40% to 80% at 5 to 9 months and failure to improve survival[1-3]; however, it still has palliative benefits and other important indications in the era of transcatheter aortic valve replacement (TAVR). The arrival of TAVR has resulted in an increase in the overall use of BAV. Currently, it is being used not only for palliation in high-surgical-risk patients, but additionally plays a diagnostic role in clarifying the significance of aortic stenosis in patients with multiple comorbidities and most commonly in "stand-alone" cases as a bridge to TAVR. Its role in TAVR includes both predilatation and postdilatation and, on occasion, annular sizing. It has also been helpful in evaluating a patient's risk for coronary occlusion with TAVR. With these broader indications has come a need for improvement in devices and technique.

CURRENT INDICATIONS FOR STAND-ALONE BAV

Current American College of Cardiology/American Heart Association guidelines are fairly restrictive and, in our opinion, should be broadened in this era of TAVR. The 2014 guidelines give stand-alone BAV a class IIb indication.[4] It is believed to be appropriate as a bridge to surgical aortic valve replacement (SAVR) or TAVR in patients with severe, symptomatic aortic stenosis (AS).

Most centers have broadened their indications for stand-alone BAV (Table 1). Multiple published experiences for indications used over the years and at Minneapolis Heart Institute (MHI) have demonstrated consistent improvement in quality of life. The patients' New York Heart Association functional class frequently improves from III/IV to I/II. The demonstrated safety of serial BAV for restenosis extends the period of enhanced quality of life. Although not proven, some authors have suggested a survival benefit with serial BAV. In addition, achieving a post-BAV aortic valve area (AVA) of 1 cm^2 has also been associated with improved longevity.[5,6] With improved technique and a decrease in complications, the volume of BAV procedures has significantly increased over the past 5 to 10 years (Table 2).[7]

The actual need for BAV bridging has not been clarified but is being used as a diagnostic tool on occasion

TABLE 1. POTENTIAL INDICATIONS FOR STAND-ALONE BAV IN PATIENTS WITH SYMPTOMATIC AS

High-surgical-risk profile secondary to comorbidities and/or frailty, plus one of the following factors: • Very limited longevity (< 1–2 y) • Noncandidate for any antiplatelet therapy secondary to high bleeding risk
Bridge to TAVR or SAVR • Diagnostic BAV in patients with severe AS and other potential causes for symptoms (ie, lung disease) • Patients with a significant degree of myocardial dysfunction, prerenal insufficiency, or other organ system dysfunctions that may be reversible with BAV • High-risk noncardiac surgery that is not elective • Patients requiring high-risk PCI before TAVR (combined BAV and PCI) • Acutely unstable patients
Adapted from Pedersen W, Goldenberg I, Ben-Dor I, Feldman T. Aortic and pulmonic balloon valvuloplasty. In: Lasala J, Rogers J, eds. Interventional Procedures for Adult Structural Heart Disease. Philadelphia: Elsevier Saunders; 2013:50–72.[7]

TABLE 2. TWO LARGE BAV REGISTRY EXPERIENCES IN THE UNITED STATES SINCE 2000[7]

	Washington Hospital Center January 2002–December 2009	MHI June 2003–February 2012
Demographics		
Patients	262	332
Procedures	301	412
Age (y)	81.7 ± 9.8	85.5 ± 6.6
STS score > 10 (%)	69.1	42.7
Female sex	145 (55.3%)	186 (56%)
Coronary artery disease	168 (64.1%)	184 (55.4%)
Patient BAV		
Total number of patients	262	332
Patient with a single BAV	223 (85.1%)	252 (75.9%)
Patients with > 2 BAVs	39 (14.9%)	80 (24.1%)
Procedural data		
Balloon size (mm)	22.9 ± 1.9	23.9 ± 1.2
Number of inflations	1.7 ± 0.9	3.2 ± 1.5
Intraprocedural hemodynamics		
Mean grade pre-BAV (mm Hg)	46.3 ± 19.7	49.8 ± 16.7
Mean grade post-BAV (mm Hg)	21.4 ± 12.4	25.2 ± 10.4
AVA pre-BAV (cm^2)	0.58 ± 0.3	0.64 ± 0.2
AVA post-BAV (cm^2)	0.96 ± 0.3	N/A
Echocardiography		
Mean grade pre-BAV	42 ± 13.9	43.55 ± 13.77
Mean grade post-BAV	31.9 ± 11.8	26.78 ± 11.18
AVA pre-BAV (cm^2)	0.68 ± 0.15	0.61 ± 0.16
AVA post-BAV (cm^2)	0.87 ± 0.19	0.84 ± 0.3
LVEF pre-BAV (%)	45.4 ± 18.4	43.81 ± 12.84
LVEF post-BAV (%)	47 ± 18	45.74 ± 9.09
AR grade pre-BAV (%)	0.8 ± 0.7	1.1 ± 0.8
AR grade post-BAV (%)	1 ± 0.7	0.9 ± 0.6
Serious adverse events		
Intraprocedural death	5 (1.6%)	9 (2.2%)
Stroke	6 (1.99%)	5 (1.2%)
Coronary occlusion	2 (0.66%)	1 (0.2%)
Emergent interventions	Hypotensive requiring CPR, intubation, or cardioversion: 5 (1.6%)	Intubations: 7 (2.11%); cardioversions: 6 (1.81%); emergent IABPs: 5 (1.5%)
Tamponade	1 (0.3%)	2 (0.5%)
PPM	3 (0.99%)	2 (0.5%)
Vascular complications	Requiring any intervention: 21 (6.9%)	Requiring surgical intervention: 3 (0.7%)

Abbreviations: AR, aortic regurgitation; CPR, cardiopulmonary resuscitation; IABP, intra-aortic balloon pump; MR, mitral regurgitation; N/A, not available; STS, Society of Thoracic Surgeons.
Adapted from Pedersen W, Goldenberg I, Ben-Dor I, Feldman T. Aortic and pulmonic balloon valvuloplasty. In: Lasala J, Rogers J, eds. Interventional Procedures for Adult Structural Heart Disease. Philadelphia: Elsevier Saunders; 2013:50–72.[7]

for ruling out comorbidities as the most significant cause of the presenting symptoms. Additional indications for BAV include its use as a bridge in patients with extreme left ventricular (LV) dysfunction, refractory chronic heart failure, or hemodynamic instability.

CURRENT INDICATIONS FOR BAV DURING TAVR

Accepted standards for TAVR predilatation primarily depend on the specific transcatheter heart valves being deployed and operator preference. For balloon-expandable valves (ie, Sapien XT and Sapien 3, Edwards Lifesciences), predilatation is more uniformly carried out with undersized 20- or 22-mm balloons, as this allows easier valve crossing. Predilatation is generally not performed during the deployment of self-expanding valves (ie, CoreValve, Medtronic). We have found that without predilatation, CoreValve crosses the native valve stenosis without issue, and deployment seems more secure during positioning. Predilatation has not been proven to increase the incidence of complete heart block after CoreValve implantation.

Paravalvular leak (PVL) has been a limitation in offering TAVR to lower-risk patients. Although there has been substantial improvements in the balloon-expandable Sapien 3, PVL still remains an issue with the self-expandable CoreValve device and in early evaluation of the Evolute device (Medtronic). Moderate or greater (and possibly even mild) PVL after TAVR has been associated with increased short- and long-term mortality.

The largest meta-analysis of TAVR outcomes from 16 studies of 3,519 patients reported an incidence of 7.4% for moderate or greater PVL.[8] The broad range of reported PVL has been, in part, related to variability in the imaging technique used in grading PVL. Transcatheter deployment of the aortic valve prosthesis in the presence of calcification at the landing zone can result in an incomplete seal between the prosthetic valve and the native leaflets, annulus, and LV outflow tract.[9,10] PVL after CoreValve implantation occurred in 59 of 120 patients (49.2%) in the randomized CHOICE trial.[11] Further balloon postdilatation (BPD) as a surrogate for PVL occurred in 50 of 276 patients (18.1%) who underwent CoreValve implantation in the pooled analysis from two experienced centers in Germany[12] and 272 of 1,376 patients (19.8%) who underwent CoreValve implantation at seven Italian centers, with data prospectively collected in the Clinical Service Project.[13]

In these studies, successful achievement of PVL grade 1+ or less after BPD with standard balloons ranged from 30% to 63%. By consensus, standard balloon diameters used for BPD after CoreValve implantation should not exceed the mean annulus diameter.

At two centers (San Raffaele Scientific Institute in Milan, Italy, and MHI in Minneapolis, Minnesota), a consecutive series of 11 patients underwent BPD with the new V8 hourglass-shaped balloon (InterValve, Inc.), and 10 of the 11 patients (91%) were successfully reduced to a PVL grade 1+ or less (A. Latib, MD, unpublished data, 2015). The V8 balloon retains its hourglass shape throughout inflation, permitting consistent locking on the underlying native annulus at the balloon waist. The proximal bulb segment enables native leaflet hyperextension into the aortic sinuses. The more compliant waist segment allows for incremental dilatation at the calcified leaflet bases of the annulus and flaring along the infra-annular margin.

The V8 device is relatively short in length (32 and 28 mm). Precise, volume-driven segment diameters are achieved, and rapid inflation-deflation times of approximately 2 seconds limit systemic hypotension. A 24-mm-length balloon is now undergoing development with an 8-mm-length proximal segment and a 4-mm-length distal segment to limit postdilatation to the infra-annular region and maintain balloon expansion with the distal stent margin. In this 11-patient BPD series, there were no complications (eg, annular dissection or stroke). The new permanent pacemaker (PPM) implantation rate was 20%, which is not different from other trials, including the recently published ADVANCE II trial, which was designed to minimize new PPM implantation rates.[14]

The lack of radial force with self-expanding valves is believed to create underlying gaps or gutters secondary to nonuniform apposition abetting noncompliant tissue. The shape of the hourglass balloon appears to result in focused dilatation, yielding more aggressive remodeling of the underlying calcified leaflets and perianular calcification while sparing the annulus from excessive dilatation pressure. This allows for more optimal expansion of the self-expanding stent frame and improved sealing to effectively reduce PVL.

BAV IN UNIQUE CLINICAL SETTINGS

BAV in Pregnancy

Many patients with severe AS can be managed medically. BAV is generally performed during pregnancy in the presence of persistent heart failure after failed medical therapy. Untreated, severe AS is associated with an increase in maternal and fetal risk. In one study, neonatal complications occurred in 25% of 49 pregnancies.[15] In another study, maternal complications occurred in 23 of 49 (40%) patients, most commonly overt heart failure.[16] AS in younger adults is often rheumatic or congenital in origin, resulting in a more durable outcome.

BAV Prior to Noncardiac Surgery

Patients with severe AS requiring nonelective surgery are generally acceptable risk without BAV intervention. However, in patients with decompensated heart failure or hemodynamic instability, BAV is appropriate and can be safely carried out. The threshold to proceed with preoperative BAV should be lowered in the presence of severe LV dysfunction or prior to operations where severe blood loss is likely.

Repeat BAV for Aortic Valve Restenosis

Now that TAVR is an option, the need for repeat BAV has markedly diminished. Nevertheless, a substantial experience published from multiple centers has demonstrated repeat BAV to be effective and safe. It has been noted in individuals who have undergone multiple BAV procedures (ie, three or more) that there appears to be a smaller increase in AVA and an increasing incidence of aortic regurgitation.[5,6,17] In addition, the duration of symptomatic improvement between interventions appears to be reduced.

BAV in Patients With Severe LV Dysfunction

With appropriate technique, BAV can be performed in patients with advanced LV dysfunction with a low incidence in mortality. In one series of 55 patients with a left ventricular ejection fraction (LVEF) of < 40% who underwent BAV, the mean LVEF improved from 29% ± 7% to 34% ± 9%.[18] Patients with extremely reduced LVEF (ie, ≤ 20%) are often denied SAVR, as well as TAVR. The risk of BAV to assess the likelihood of improvement in the presence of extreme LV systolic dysfunction has not been extensively evaluated. In these patients, BAV may serve as a diagnostic bridge to SAVR or TAVR with significant improvement in LVEF.

Some investigators have reported that in a small number of patients, BAV can be carried out with LV mechanical support. We reported on our experience with 15 consecutive patients who had undergone BAV with an LVEF of < 20% in the absence of LV mechanical support.[19] The mean age was 83.1 ± 10.5 years, and the mean LVEF was 16% ± 2.7%. Forty-three percent of patients had coronary artery disease. The mean balloon diameter was 23.6 ± 1.4 mm, and the number of inflations was 3.3 ± 1.4. There were no intraprocedural mortalities; however, two patients required the use of an emergent intra-aortic balloon pump. The total 15 patients were divided into two groups: in group 1, eight patients had a postoperative LVEF that remained < 20%, and group 2 had a postoperative LVEF of ≥ 20%. The seven patients in group 2 had a mean LVEF of 25%.

Variables associated with this more significant improvement in LVEF include:

- Absence of coronary artery disease
- Higher preoperative LVEF
- Post-BAV increase in AVA of ≥ 0.2 cm^2

Relevant techniques in unsupported BAV exclude:

- Frequent intravenous boluses of phenylephrine to preserve a systolic blood pressure of ≥ 90 mm Hg
- Intravenous inotrope, generally dopamine for a baseline cardiac index of ≤ 2 L/min/m^2
- Availability of an intra-aortic balloon pump in the room
- No further BAV if systolic blood pressure cannot be brought up to ≥ 90 mm Hg promptly with phenylephrine

BAV in Patients With Aortic Insufficiency

BAV is not strictly contraindicated in the presence of aortic insufficiency (AI). Severe AI as a complication of BAV is rare (< 2%). The catastrophic consequences of acute, severe AI have led to avoidance of BAV in patients with moderate or less AI. Patients with 2+ AI (and on occasion, 3+) may actually improve following BAV secondary to improved leaflet mobility. In a series of 73 patients with moderate or severe AI, the degree of AI post-BAV was improved or unchanged in 65 patients (89%) and only worsened by one grade in eight patients (11%).[20] Only one patient died as a result of acute, severe AI. In five patients with severe AI post-BAV, the etiology was believed to be a "bent" valve leaflet that remobilized through manipulation using a pigtail catheter stiffened with a guidewire. It should be noted that in 98% of the patients, a 20-mm balloon was used.

Combined BAV and Percutaneous Coronary Intervention

Although this combined procedure is much less commonly indicated, it can be carried out safely. Fifty-six cases of combined BAV and percutaneous coronary intervention (PCI) were found in the MHI database. There was one perioperative myocardial infarction and no mortalities. Of these 56 patients, 37 (66%) underwent single-vessel stenting, 15 (27%) underwent double-vessel stenting, and four (7%) underwent triple-vessel stenting.[21] Complex lesions were usually avoided, and PCI was performed on vessels subtending larger myocardial territories. Generally, coronary stenting was performed before BAV. PCI alone has been demonstrated in 254 patients with severe AS to be reasonably safe, resulting in a 4.3% mortality rate at 30 days.[22] In general at MHI, we would

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perform this simultaneous procedure in the presence of decompensated heart failure or severe LV dysfunction as a potential bridge to TAVR.

CONCLUSION

BAV is now being performed more frequently in the TAVR era, but the indications have shifted substantially. BAV is less commonly carried out as a stand-alone procedure. It is currently used in the TAVR perioperative period, either for predilatation or postdilatation in the presence of significant PVL. BAV in the latter is more commonly used following deployment of self-expanding valves for the purpose of remodeling the underlying calcified tissue. ■

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