Balloon Aortic Valvuloplasty in the TAVI Era

A review of current technique and uses in stand-alone, bridging, and predilation settings.

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Balloon aortic valvuloplasty (BAV) as a treatment for severe aortic stenosis (AS), a common disease of the elderly, was introduced by Dr. Cribier in 1985.[1] The initial experience demonstrated the technical feasibility, acceptable safety, and a fairly consistent, modest improvement in valve areas. In spite of only modest valve area improvement, patients experienced significant symptomatic benefit. The result led to a prematurely enthusiastic embrace by interventional cardiologists. However, the rapid recognition of extremely high restenosis rates within a year of the procedure quickly tempered enthusiasm. A subsequent large series showed high restenosis rates and a failure to improve survival despite its palliative benefits.[2-4] Echocardiographic restenosis rates of 40% to 80% at 6 to 9 months, as well as rates consistently > 80% at 1 year, were reported. One-year mortalities have generally ranged from 25% to 45%. However, the clinical lag in recurrence of baseline symptoms extends 6 to 12 months beyond hemodynamic restenosis. Therefore, a quality-of-life (QOL) benefit after BAV will usually last 1 to 2 years in these elderly patients, who are generally less concerned about longevity.

The treatment of choice for severe, symptomatic AS has remained surgical aortic valve replacement (AVR). However, with the rapidly expanding population of patients in their 80s and 90s, who often carry the burden of significant comorbidities, a resurgence of palliative valvuloplasty has taken place during the past decade. Reported series in octogenarians and nonagenarians have shown its relative safety, with procedural mortalities in the range of 2%.[5,6] Elderly patients with high surgical risk or Society of Thoracic Surgeons (STS) scores of > 10% and the probability of prolonged postoperative recovery generally find the risk:benefit ratio of aortic valvuloplasty quite favorable. Furthermore, from the patient's perspective, a strategy of serial BAV has resulted in more protracted periods of QOL enhancement.

The arrival of transcatheter aortic valve implantation (TAVI) is timely, particularly given the increase in life expectancy and the need for a more durable alternative to BAV in poor surgical candidates. The prevalence of AS in patients older than 75 years is reported to be 4.6%.[7] The first-in-man implantation was successfully performed in 2002 by Cribier et al.[8] Progressive technological improvements in both of the stented valve implants and delivery systems, along with operator experience, have resulted in a logarithmic growth in TAVI since CE Mark approval was obtained in Europe. Two valves have emerged early and include the Sapien balloon-expandable stent valve (Edwards Lifesciences, Irvine, CA) and the self-expanding CoreValve device (Medtronic, Inc., Minneapolis, MN). Implant success

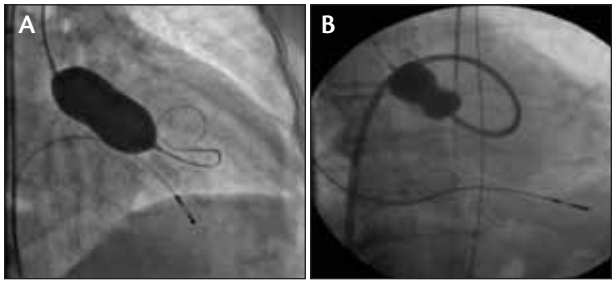

Figure 1. Retrograde arterial approach using a standard aortic balloon (A). Antegrade transseptal approach using an Inoue balloon (Toray International America, Inc., Houston, TX) (B).

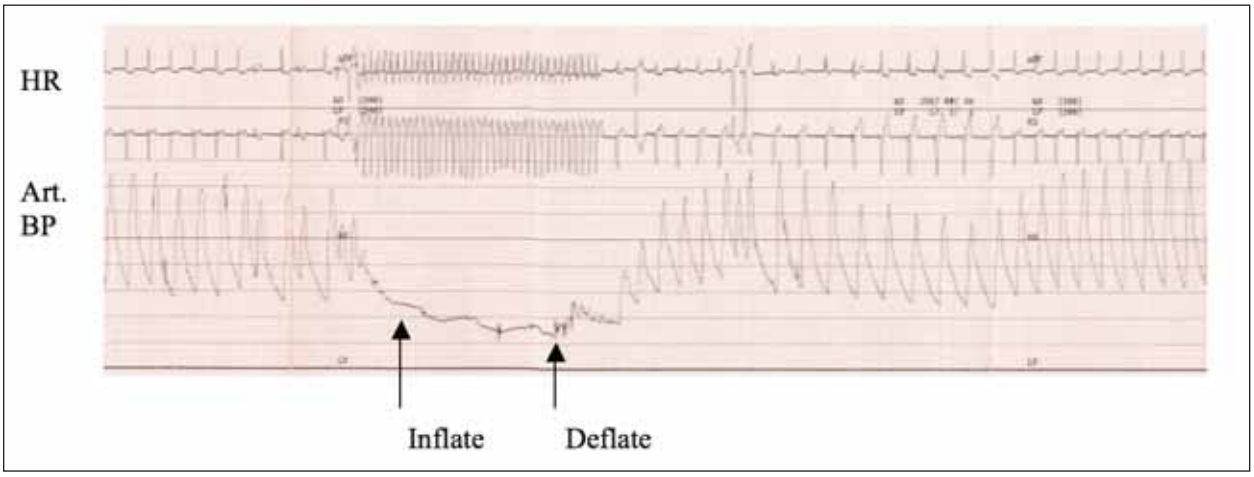

Figure 2. Rapid ventricular pacing. Art., arterial; BP, blood pressure; HR, heart rate.

rates are now reported to be > 90%, procedural mortality is down to 2%, and 30-day mortality rates are < 10% in appropriately selected patients.[9,10] Acute hemodynamics after implantation yield mean gradients of < 10 mm Hg and aortic valve areas > 1.5 cm^2. Limited midterm follow-up has not shown any valve failures.[11]

BAV is an essential procedural step during TAVI to predilate the stenosed leaflets for easier transcatheter delivery. Additionally, BAV during predilation can be used for valve-sizing strategies. BAV will undoubtedly be used not only as a bridge to surgical AVR, but to TAVI as well. Even at centers in which TAVI has become an established practice, significant proportions of patients are deemed to be unsuitable for TAVI and are treated with BAV.[12]

PATIENT SELECTION

Current indications for BAV based on American College of Cardiology/American Heart Association guidelines[13] will soon evolve. The substantial increase in BAV volumes during the past 5 to 10 years, reflecting less stringent patient selection, has come about for two primary reasons. The first is based on a realization that a substantial population of comorbid and elderly patients who are poor candidates for surgical AVR derive a significant palliative benefit. It has been shown in multiple published experiences that New York Heart Association (NYHA) class can be significantly improved.[6,14-16] The demonstrated safety in serial BAVs for patients with recurrent restenosis extends the opportunity for achieving longer periods of enhanced QOL even further. Although unproven, some authors have suggested a survival benefit as well.[12,14] Second, the option for TAVI in these poor-surgical-risk groups has had an explosive impact on the use of BAV. BAV is not only essential for predilation but has now been reported to successfully bridge patients to TAVI.[16,17] Patient groups that were initially too unstable in one series underwent successful TAVI after a mean interim period of 59 ± 57 days.[16] The precise role of BAV in this regard will obviously require a broader experience.

In the pre-TAVI era, we had published our indications for stand-alone BAV[18] and have subsequently modified them (see *Severe, Symptomatic AS Patients in Whom Balloon Aortic Valvuloplasty Should Be Considered* sidebar). We did not include patients undergoing predilation for TAVI on this list.

SEVERE, SYMPTOMATIC AS PATIENTS IN WHOM BALLOON AORTIC VALVULOPLASTY SHOULD BE CONSIDERED

- Bridge to surgical AVR or TAVI in hemodynamically unstable patients or patients with severe left ventricular dysfunction
- Diagnostic clarification in symptomatic patients with multiple severe disease processes such as lung disease
- Significantly increased perioperative AVR risk (STS score >10%–15%)
- Anticipated survival < 3 years
- Age ≥ 85 years and strongly opposed to surgical AVR
- Severe comorbidities such as porcelain aorta, extensive chest radiation, multiple prior open-chest cardiac surgeries, extensive lung disease for which the surgeon refuses to operate
- Disabling neuromuscular or arthritic conditions that would impair postoperative rehabilitation

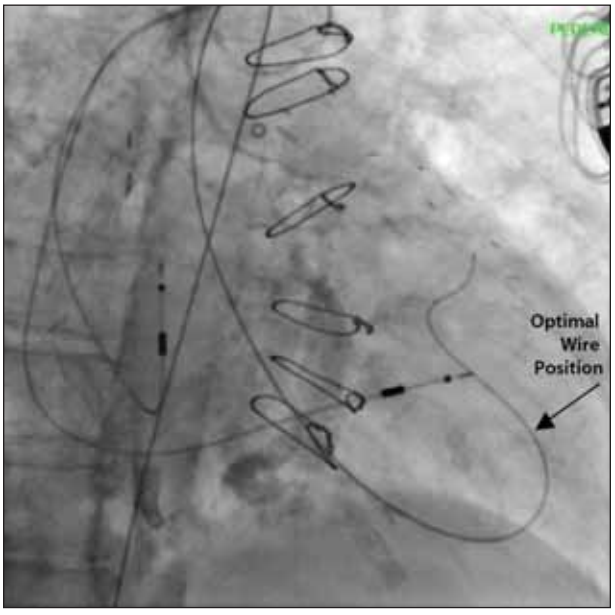

Figure 3. RAO projection.

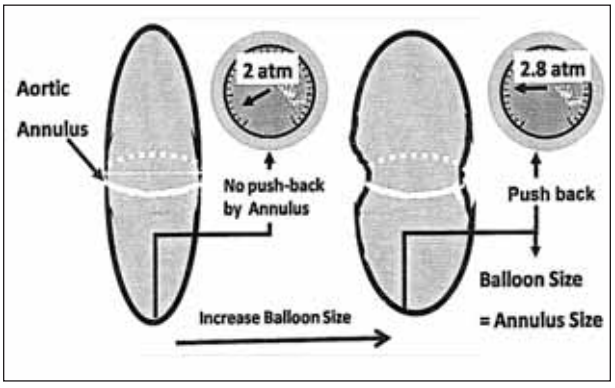

Figure 4. Aortic annulus sizing by BAV catheter. Reprinted from JACC Cardiovascular Interventions, 3/1, Babaliaros VC et al., Use of Balloon Aortic Valvuloplasty to Size the Aortic Annulus Before Implantation of a Balloon-Expandable Transcatheter Heart Valve, 114-118, Copyright © (2010), with permission from Elsevier.

MECHANISMS OF ACTION

The effects of BAV on stenosed aortic valves are poorly understood, but several mechanisms appear likely.[19] Primarily, balloon-induced fracturing of calcified nodules creates hinge points,[20] which along with the creation of cleavage planes in collagenous stroma, results in improved leaflet flexibility and valve opening. Separation of fused leaflets is uncommon given its infrequent occurrence in this patient population with calcific aortic stenosis. Enhanced compliance or stretching of the adjacent annulus and calcified aortic root has also been suggested.[18]

TECHNIQUE

There are two balloon aortic valvuloplasty techniques (Figure 1), both of which are well described in the literature.[21,22] The retrograde technique is the simplest and the one most commonly used. The antegrade technique, which we will not discuss in detail in this article, is carried out percutaneously from the femoral vein or surgically from the transapical approach.

Antegrade Approach

The transfemoral antegrade approach requires transseptal access to the left heart and a transcirculatory wire loop for balloon delivery, which is technically demanding. The predominant advantage remains its ability to avoid placement of a large sheath introducer in diseased peripheral arteries and thus avoiding the more common bleeding and ischemic complications seen with retrograde arterial access. Nonrandomized studies have shown a more effective valve opening with the antegrade approach when used in conjunction with the Inoue balloon. It is suggested that the bulbous distal balloon segment is able to hyperextend the valve leaflets more broadly into the aortic root sinuses of Valsalva. One series reported a 20% greater valve area for patients undergoing antegrade BAV with an Inoue balloon compared to a retrograde approach using standard aortic balloons.[21]

Retrograde Approach

This technique is generally carried out from the transfemoral artery approach. Good technique in ensuring common femoral access via anterior wall puncture is critical for minimizing procedural and postprocedural complications. A test contrast injection with the initial arterial puncture can ensure correct positioning before placing larger sheaths. Percutaneous preclosure sutures can be deployed after the initial placement of a 6-F sheath. One method uses two 6-F ProGlide devices (Abbott Vascular, Santa Clara, CA) placed sequentially at 90º angles for suture deployment, after which, a larger sheath is exchanged for the initial 6-F sheath. Alternatively, a single 10-F Prostar device (Abbott Vascular) can be used. A 10- to 12-F sheath is then placed, depending on the balloon that is selected. Intravenous heparin is administered to achieve an activated clotting time of 250 to 300 seconds. All patients should be pretreated with 325 mg of aspirin. Coronary angiography and bilateral heart catheterization is then carried out, and baseline hemodynamics are recorded.

The aortic valve is crossed with an Amplatz left 1 or 2 diagnostic catheter (Boston Scientific Corporation, Natick, MA). In a left anterior oblique projection, a brief cine run for two to three cardiac cycles should be captured to evaluate the location of systolic leaflet separation. Positioning the

TABLE 1. PREDICTORS OF PROCEDURAL MORTALITY

Predictors of Mortality	Nonpredictors of Mortality	
• Measures of AS severity	• Age	• Balloon diameter
	• LVOT diameter	• LVEF
	• STS score	• No. of inflations

Variable	PM Group (N = 7) (Mean ± SD)	Non-PM Group (N = 203) (Mean ± SD)	*P* Value
Age in years: mean (SD)	88.3 ± 3.1	8.6 ± 6.4	.55
STS score	11.1% ± 4.6%	12.6% ± 5.7%	.36
Pre-BAV LVEF (%)	53.6 ±13.7	49 ± 16.6	.58
Pre-BAV mean gradient (mm Hg)	64.3 ± 20.3	40 ± 18.8	.051
Pre-BAV AVA (cm^2)	0.4 ± 0.11	0.6 ± 0.4	.009
LVOT diameter (mm)	19.8 ± 1.9	20 ± 1.6	.45
Maximum balloon diameter (mm)	23.3 ± 0.5	23.0 ± 1.5	.14
Number of inflations	4 ± 2.7	3.8 ± 2.2	.9

Abbreviations: AVA, aortic valve area; LVOT, left ventricular outflow tract; LVEF, left ventricular ejection fraction; PM, procedure mortality; SD, standard deviation.

TABLE 2. SUCCESSFUL BAV AS A PREDICTOR OF IMPROVED LVSF IN PATIENTS WITH LVEF ≤ 25%

Variable	Group 1 Successful BAV (n = 12) (Mean ± SD)	Group 2 Unsuccessful BAV (n = 8) (Mean ± SD)	*P* Value
Age in years	85.1 ± 6.8	83.7 ± 3.9	.63
CAD, n (%)	8 (66.7)	3 (42.9)	.38
STS score	14 ± 6	20 ± 5.1	.29
Δ AVA (cm^2)	0.39 ± 0.17	0.06 ± 0.10	.002
Pre-BAV % LVEF	19.8 ± 4.7	19.6 ±4.2	.95
Post-BAV% LVEF	30.8 ± 12.3	23.9 ± 1.8	.2
Δ % LVEF	11.3 ± 12	4.6 ± 7.8	.21
6-month mortality, n (%)	3 (25)	3 (42.9)	.62

Abbreviations: CAD, coronary artery disease; LVSF, left ventricular systolic function.

delivery catheter within the systolic jet, which is confirmed by catheter tip vibration, can reduce the time required to successfully cross the valve. A straight-tipped wire is used to probe the valve and access the left ventricle. Switching to a right anterior oblique (RAO) projection is helpful for exchanging a dual-lumen pigtail catheter or other diagnostic catheter over an exchange-length wire, after which, peak and mean systolic valve gradients are measured.

A bipolar pacing lead is then advanced into the right ventricle, and stable capture thresholds are documented. A brief pacing run should be carried out at 180 to 220 beats per minute, ensuring one-to-one capture and verifying that the systolic blood pressure decreases below 60 mm Hg. Lower heart rates are usually inadequate for limiting systolic flow and thus are less likely to maintain a stable balloon position during inflation. Not uncommonly, 2:1 exit block may occur when attempting to pace at rates of 200 beats per minute or greater. Pacing at 180 beats per minute may achieve 1:1 capture, and if the decrease in blood pressure is not sufficient, the rate can be rapidly increased to 200 beats per minute with preservation of 1:1 capture before initiating balloon inflation (Figure 2).

A 0.035-inch, extra-stiff guidewire with a soft tip is placed in the left ventricle. The distal, softer wire tip is first shaped into a broad loop and draped across the anterior left ventricular wall and apex through the diagnostic catheter under fluoroscopy in an RAO projection (Figure 3).

Preserving this wire position is crucial in preventing left ventricle (LV) perforation during subsequent balloon inflations. The diagnostic catheter and sheath are then removed

FREQUENTLY ASKED QUESTIONS REGARDING BAV

What do I need to consider in the differential diagnosis of persistent hypotension immediately following balloon inflation?

Answer:

- Acute LV systolic failure (especially in patients with baseline left ventricular ejection fraction [LVEF] < 30%)
- LV perforation with tamponade
- Ruptured valve annulus or aortic dissection with or without tamponade
- Leaflet avulsion and severe aortic insufficiency
- Blood loss from expanding hematoma or retroperitoneal bleeding
- Vagally mediated hypotension
- Bradycardia secondary to heart block

Can I predict procedural mortality in hemodynamically stable patients?

Answer: Possibly. Two hundred ten consecutive patients who underwent BAV from 2003 to 2008 at our institution were evaluated retrospectively for clinical and procedural predictors of mortality.[23] Findings are listed in Table 1.

Interestingly, in this one retrospective series, clinical parameters including age, LVEF, and STS score did not predict mortality. Severity of AS was the only significant predictor, especially in patients with AVAs < 0.4 cm^2. It is unknown if less aggressive dilation with smaller balloon sizes would be safer.

Can successful BAV predict the likelihood of systolic recovery in patients with critically severe LV dysfunction?

Answer: Probably. Twenty patients were identified from our institution's BAV database from 2003 to 2008 with LVEFs ≤ 25% (mean LVEF, 20%).[24] Previous studies have focused on BAV safety and outcomes in patients with more moderate degrees of LV dysfunction. Patients in our study were divided into two groups based on BAV success defined by a ≥ 35% improvement in AVA on predischarge echocardiography. Findings are presented in Table 2.

The findings showed a trend toward a greater increase in LVEF in the successful BAV group (55% improvement) than in the unsuccessful BAV group (20% improvement), although this was not statistically significant with these small patient numbers. Patient numbers were also too small to determine any effect underlying ischemia had on these trends. There was no procedural mortality in patients with LVEF ≤ 25%. From a diagnostic standpoint, the standard should remain dobutamine echocardiography for determining LV viability and potential for recovery after TAVI or AVR.

Can coronary percutaneous coronary intervention (PCI) be safely carried out with BAV as a combined procedure?

Answer: Yes, in appropriately selected lesions, but the clinical benefits are unknown. From 2003 to 2008, 17 patients (mean age, 86 ± 6 years) with severe AS and coronary artery disease underwent combined BAV and coronary stenting. Twelve patients underwent single-vessel stenting, four patients underwent two-vessel stenting, and one patient underwent three-vessel stenting. Treated lesions included saphenous vein grafts, as well as native coronary stenosis. Thirteen of the 17 patients underwent PCI before BAV. Patients who underwent BAV first presented to the cardiovascular laboratory in a hypotensive state. The decision to proceed with PCI was based on the operator's perception that it would contribute to symptomatic benefit. Operators appeared to select larger vessels and less complex lesions based on the predominance of class A and B1 lesions treated. There were no myocardial infarctions, strokes, or procedural or in-hospital mortalities.[25]

What are the follow-up needs for these patients after BAV?

Answer:

- Postoperative maintenance on aspirin is recommended.
- Serial brain natriuretic peptides are useful in guiding diuretic management and predicting symptom recurrence.
- Angiotensin-converting enzyme inhibitors and beta blockers should be used in patients with associated cardiomyopathy.
- Patients are seen in the valve clinic 30 days after BAV and undergo blood work including electrolytes, blood urea nitrogen, creatinine, hemoglobin, and brain natriuretic peptide.
- Follow-up is recommended every 6 months, with echocardiography performed sooner with symptom recurrence.
- Patients and referring physicians are instructed that BAV can be repeated for recurrent symptoms without additional risk and, if appropriate, TAVI, as it becomes available in the United States.

while preserving wire position in the LV. Balloon sizing is generally more aggressive in stand-alone BAV, choosing balloon diameters at the beginning that will achieve a 0.9:1 or 1:1 balloon-to-annulus ratio. A contrast-diluted 1:9 ratio for balloon inflation is used to minimize viscosity and thus inflation and deflation times. Most balloons take 25 to 30 mL of volume to fill and can be delivered with a 30- or 60-mL plastic syringe. A 10-mL side syringe can be placed with a stopcock to allow further full inflation of the balloon. After positioning the uninflated balloon markers across the valve, rapid ventricular pacing is initiated, and balloon inflation is carried out as briskly as possible, making balloon catheter adjustments to preserve stable balloon position throughout inflation. Generally, no more than two to three inflations with each balloon size are carried out before upsizing if needed. It is crucial to allow systemic blood pressures to return to baseline before proceeding to the next inflation. Intravenous phenylephrine in 100- to 200-µg boluses can be used for significant delays in blood pressure recovery.

The diagnostic catheter is then exchanged for the balloon, and valve gradients are remeasured. Although not always achievable, our target is to achieve a 50% reduction in mean gradient. If needed, 1-mm increments in balloon diameter sizes can be used for judicious use in carrying out further inflations. It is important to remember that valve gradients can be reduced not only secondary to improved valve opening but can result from a transient reduction in stroke volume. Thus, repeat cardiac output measurements should be obtained to confirm an adequate increase in valve area. At this point, the catheters are removed, and suture closure is carried out with a guidewire in place. When hemostasis appears to be good, the guidewire is removed. Protamine can be administered for heparin reversal at this point if desired. Patients are then maintained on 3 to 4 hours of bed rest.

Procedural Outcomes

Reported postprocedural improvements in valve area are variable and have predominately ranged from 0.3 to 0.4 cm^2.[4,14-16,20,21,26-28] Factors that appear to influence results include the nature of underlying valve pathology, severity of preoperative stenosis and calcification, and levels of aggressiveness in balloon sizing. Criteria for successful BAV have, in general, included a 30% increase in aortic valve area (AVA). However, we should not lose sight of the most relevant measure of success in palliative procedures, which are QOL measures such as NYHA function class and hospital readmissions, both of which are improved with BAV. Patients undergoing BAV are usually NYHA functional class III to IV at baseline, the majority of whom experience improvement to class I to II.[6,16,17,24] The most important predictor of event-free survival after BAV has been left ventricular function at baseline.[29] BAV may be repeated when symptoms recur, as long as aortic insufficiency is not greater than mild to moderate. Many patients have periods of improved QOL for a year or more after each BAV procedure.[12,14]

The most relevant procedural complications that need to be reviewed with patients prior to obtaining consent include a procedural mortality rate ranging from 1% to 3%.[5,14,24,23] Strokes complicating BAV procedures have consistently ranged from 1% to 2%, and severe aortic insufficiency has ranged from 1% to 2%.[15,24,30] The reported incidence of vascular complications related to the percutaneous site depends on how they are defined and include hematoma, need for blood transfusion, and surgical repair. With the introduction of percutaneous closure devices, the need for surgical repair has been reduced from an incidence of 5%[14] to < 1% in some case series.[24,31]

BAV PREDILATION AND USE IN PATIENT ASSESSMENT FOR TAVI

BAV in TAVI procedures serves to predilate the valve and thus enhance transcatheter delivery of the valve implant. BAV also offers the opportunity to minimize any likelihood of coronary occlusion, as well as an opportunity for annular sizing. A separate pigtail catheter is positioned in the aortic root, and during balloon inflation with full leaflet expansion, contrast is injected through the pigtail. Both coronaries should be observed to fill with contrast without aorto-osteal impingement by the flared valve leaflets. If significant coronary obstruction is documented, TAVI is either aborted, or coronary access is preserved with a guidewire before TAVI to permit subsequent stent rescue.

Transesophageal echocardiographic measurement, as well as preoperative cardiac CTA, appear to have limitations in precise annular sizing.[32] Although their impact on TAVI outcomes has not been clarified, its relevance for undersizing or oversizing devices seems obvious. Two methods have now been described to aid in more accurate valve size selections.

One method described by Babaliaros et al uses balloon sizing as an adjunct to transesophageal echocardiography for aortic valve annular sizing and device selection.[32,33] In brief, a noncompliant balloon is used in tandem with a pressure manometer on an indeflator. On a sterile table, balloons are inflated to achieve 2 atm of intraballoon pressure, and the inflation volume is noted. Calipers are used to determine the balloon diameter achieved. The balloon is then deflated and positioned across the patient's aortic valve, after which it is reinflated with the same volume of dilute contrast. If just 2 atm of pressure are recorded, the balloon diameter is smaller than the annulus. On the other hand, if the intraballoon pressure exceeds 2 atm (ie, additional intraballoon pressure), the annular size has been reached or exceeded by the balloon diameter (Figure 4).

In using this strategy in a reported series of 27 patients, the authors found this technique helpful in selecting the appropriate valve size in 26% of patients.[33] There were no complications using this technique.

Dr. Cribier has described a different technique, whereby, if contrast is prevented from regurgitating into the LV with an aortic root injection around an inflated aortic valve balloon of known diameter, more precise confirmation of annular size can be made for valve selection.[34] As a broader range of transcatheter valve sizes becomes available, these techniques may have even greater relevance.

CONCLUSION

BAV is experiencing a substantial resurgence. It is now used not only in aortic valve predilation for TAVI but has taken on an expanded role with a broader recognition of its palliative benefits and means for a bridge to TAVI or AVR. With broader adoption of BAV among less-experienced interventionists and cardiac surgeons, iterative device developments will be helpful in making this procedure more controlled and precise. The opportunity to simultaneously size the annulus during BAV has been recognized and deserves further emphasis. ■

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