Balloon Valvuloplasty

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Balloon valvuloplasty techniques and equipment have continued to evolve over the last two decades. With this expanded experience, there has been refinement in patient selection and a clearer understanding of the benefits, limitations, and long-term results of balloon valvuloplasty. In this chapter the mechanisms, indications, techniques and clinical results of balloon valvuloplasty of the mitral, pulmonic, and aortic valves are described.

PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY

Percutaneous mitral valvuloplasty is an important therapeutic tool in the treatment of rheumatic mitral stenosis. Although the prevalence of rheumatic heart disease has declined significantly in the United States, this procedure remains an important therapeutic option for the symptomatic patient with mitral stenosis. In developing countries where rheumatic heart disease is very prevalent, percutaneous mitral valvuloplasty has emerged as the treatment of choice for mitral stenosis (1–3).

Mechanisms

Percutaneous mitral valvuloplasty should perhaps more appropriately be called percutaneous mitral commissurotomy, because the balloon dilatation improves the valve orifice by opening the fused mitral commissures. As shown by echocardiographic, fluoroscopic, and anatomic studies, the expanding balloon splits fused commissures in much the same way as a surgical commissurotomy (4,5).

Patient Selection

Patients should be selected for percutaneous mitral valvuloplasty based on both clinical and anatomic factors. In almost all cases, they should be symptomatic. Mitral valve area, as measured by echocardiography and hemodynamics, should be less than 1.5 cm². If they have anatomically suitable valves, patients with pulmonary hypertension, severe mitral stenosis, and variable left ventricular function can undergo this procedure. Similarly, patients with anatomically suitable valves who have developed restenosis (commissural refusion) after prior surgical commissurotomy can undergo percutaneous mitral valvuloplasty, with results almost as good as those of previously untreated patients (6,7). Although the procedure can be performed for patients of almost any age, the best clinical results are observed in younger patients; less predictable good long-term results occur in patients older than 70 years of age, who most likely have long-standing fibrotic valves. Percutaneous mitral valvuloplasty is a particularly valuable tool for the treatment of critical symptomatic mitral stenosis in pregnant women. It can also be a life-saving emergency procedure in the patient with mitral stenosis and refractory pulmonary edema or cardiogenic shock (8).

Contraindications

Although the procedure can be performed with thrombus localized to the left atrial appendage, thrombus within the left atrium itself is a contraindication to this procedure. Moderate or greater mitral regurgitation (2+ on a scale of 0 to 4, determined angiographically) is also a contraindication to percutaneous mitral valvuloplasty. Patients with mitral stenosis and severe coronary artery disease or aortic or tricuspid valve lesions that require cardiac surgery should not undergo a percutaneous mitral commissurotomy.

Anatomic Factors in Patient Selection for Balloon Mitral Valvuloplasty
Mitral balloon valvuloplasty in a 72-year-old woman who presented with progressive dyspnea on exertion. Her hemodynamic evaluation showed a mean mitral valve gradient of 22 mm Hg. This was reduced to 10 mm Hg after single-balloon valvuloplasty and to 4 mm Hg after double-balloon dilatation.

High-quality transthoracic and transesophageal echocardiography (TEE) is an essential part of proper patient selection. TEE before the planned valvuloplasty procedure excludes the presence of left atrial thrombus and moderate or greater mitral regurgitation. In addition to ensuring that there are no anatomic contraindications, TEE provides valuable information that helps the interventional cardiologist select patients and predict results. The ideal patient has pliable, noncalcified mitral leaflets and mild subvalvular disease. As the degree of subvalvular disease increases, the quality of the result with percutaneous mitral commissurotomy decreases. Similarly, increasing degrees of calcification of the mitral valve diminish the effectiveness of mitral valve dilatation and increase the complication rate. Although flecks of leaflet calcium can be tolerated, the presence of calcium within the commissures is particularly to be avoided. Dilatation of mitral valves with commissural calcification may lead to leaflet tearing along noncommissural lines and severe mitral regurgitation. Massive calcification of the valve and bicommissural calcification are contraindications to successful percutaneous mitral valvuloplasty.

Many find the echocardiographic scoring system of Wilkins et al. to be useful in assessing patients for percutaneous mitral valvuloplasty. This echocardiographic classification system is shown in Table 26.1. Points are given for leaflet mobility, valve thickening, subvalvular thickening, and valvular calcification. The final score is determined by adding up the points from each category. Higher scores indicate more severe anatomic disease and a lower likelihood of a successful procedure. The maximum score is 16. Percutaneous mitral commissurotomy results are generally excellent in patients with an echocardiographic score of less than 8, indicating favorable anatomy (i.e., pliable leaflets, mild or moderate subvalvular disease, and mild or absent valve calcification). A review of more than 1,500 patients undergoing balloon mitral valvuloplasty was used to develop a logistic model to improve patient selection. As expected, younger patients with echocardiographic evidence of less severe disease had a better outcome.

**Technique**

There are several basic techniques of percutaneous mitral valvuloplasty in use. The most common are transvenous antegrade techniques, using either a double balloon or the Inoue balloon system. These are the two techniques with which we have experience at the University of California, San Francisco. For the last 10 years we have been using the Inoue balloon introduced via an antegrade technique exclusively.

Retrograde transarterial techniques, used alone or in combination with antegrade (transseptal puncture) techniques, have been used in some centers. They offer the advantage of not requiring transseptal puncture or using only minimal dilatation of the intraatrial septum. Disadvantages of these techniques include the opportunity for arterial injury because of the larger balloons used. In addition, the procedures can be technically difficult and time-consuming. More common techniques are the transvenous antegrade approaches. The double-balloon technique uses a double-balloon guidewire system from the femoral vein to the left atrium, across the mitral valve, and to the left ventricle. The two balloons are then inflated simultaneously across the mitral valve. Figure 26.1 illustrates the two-balloon technique. In this patient the mitral valve was first dilated with a single balloon, then two balloons were used to achieve the desired hemodynamic result. The double-balloon technique, when properly performed, results in excellent improvement in mitral valve area. Multiple studies have shown no significant difference in hemodynamic results (mitral valve gradient or mitral valve area) after the procedure between the double-balloon technique and the Inoue balloon system. In our experience, the Inoue balloon technique is faster and less cumbersome and usually requires less fluoroscopy time. The Inoue balloon allows simple upsizing of the balloon without its withdrawal from the left atrium, and this is an important advantage if larger balloon sizes are needed. The Inoue balloon system may result in a slightly higher incidence of mitral regurgitation.

**FIG. 26.1.**

Mitral balloon valvuloplasty in a 72-year-old woman who presented with progressive dyspnea on exertion. Her hemodynamic evaluation showed a mean mitral valve gradient of 22 mm Hg. This was reduced to 10 mm Hg after single-balloon valvuloplasty (A) and to 4 mm Hg after double-balloon dilatation (B).

**Inoue Balloon Technique**
All antegrade approaches begin with the crucial step of successful transseptal catheterization. This technique, which is described in Chapter 4, not only allows access to the left atrium but also must be carried out through the proper part of the atrial septum to allow easy access to the mitral valve. After successful placement of a Mullins-type dilator and sheath into the left atrium and confirmation of its position by a hand injection of contrast material, the patient is anticoagulated with heparin. Baseline hemodynamics are then recorded, confirming the appropriate degree of mitral stenosis. Subsequently, a special heavy-duty, solid-core coiled guidewire is introduced into the left atrium, and the Mullins sheath dilator system is removed. The femoral vein and interatrial septum are then dilated with a long dilator over the coiled guidewire within the left atrium. The previously prepared, tested, and now slenderized Inoue balloon is introduced over the guidewire into the left atrium. The Inoue balloon (Fig. 26.2) is made of a nylon and rubber micromesh. The balloon has three distinct parts, each with a specific elasticity, and each part can be inflated sequentially. This allows for stable positioning of the balloon catheter across the mitral valve. After the slenderized balloon has been positioned within the left atrium, the stretching tube is removed. The preshaped “J” configuration stylet is then introduced into the Inoue balloon. We usually fill the distal portion of the balloon slightly, to aid in crossing the valve and to prevent intrachordal passage. With a combination of maneuvering the balloon catheter and rotating and withdrawing the stylet, the balloon tip moves anteriorly and inferiorly toward the mitral orifice. After the balloon catheter is across the mitral orifice, the distal portion of the balloon is inflated and the catheter is pulled back gently to confirm that the inflated portion is secure across the mitral valve.

**FIG. 26.2.**

The Inoue balloon in varying stages during deployment. 1: The balloon is stretched or “slenderized.” 2: The inner stretching tube is withdrawn, allowing the balloon to relax to its normal configuration. 3: The tip of the balloon is inflated with 2 to 3 mL of dilute contrast-saline mixture to facilitate flotation across the mitral valve without tangling in the chordae tendinae. 4: The proximal portion of the balloon is inflated. As inflation continues, the distal portion of the balloon inflates (5), and finally, the midportion of the balloon completely inflates (6). (Photography courtesy of Toray, Inc., Tokyo, Japan)

Figure 26.3 illustrates the sequential filling and positioning of the Inoue balloon. The balloon is filled to its preselected diameter, then emptied and withdrawn into the left atrium. The Inoue balloon system allows for a stepwise dilatation technique to be used. We routinely measure the pressure gradient across the mitral valve after the first balloon dilatation, and also use echocardiography in the catheterization laboratory to assess the mitral valve area and the degree of mitral regurgitation. If the first inflation has not resulted in a satisfactory increase in mitral valve area and the degree of mitral regurgitation has not increased, the balloon is readvanced across the mitral valve and inflation is repeated with the balloon diameter increased by 1 or 2 mm. This stepwise dilatation process is repeated until the desired result is achieved. The Inoue balloon comes in four sizes (24, 26, 28, and 30 mm, the size indicating the fully inflated balloon diameter), and these balloon sizes are pressure dependent, allowing the diameter to be varied up to 3 to 4 mm as required. We generally choose the initial balloon catheter size based on the height of the patient: one-tenth the height in centimeters + 10 mm. It is important to start with a small balloon size, especially for valves that are very thickened or rigid or have moderate amounts of subvalvular disease, to minimize the development of mitral regurgitation. Mitral regurgitation can still develop suddenly with as little as a 1- to 2-mm increase in diameter of inflation size. We believe that it is important to test for mitral regurgitation with Doppler echocardiography, in addition to looking for the presence and size of V-waves in the left atrial pressure tracing, before proceeding to the next inflation size. After successful mitral valve dilatation, the Inoue balloon is reslenderized by first reintroducing the guidewire and then the stretching tube. The slenderized balloon is subsequently withdrawn from the body over a guidewire. We then insert a 10F sheath into the femoral vein over the guidewire, remove the guidewire, and take the patient from the catheterization laboratory for later sheath removal.

**FIG. 26.3.**

Ballon mitral valvuloplasty in a 42-year-old man who presented with dyspnea on exertion. **A:** Distal tip of the Inoue balloon has crossed the mitral valve. **B:** With the distal tip of the balloon filled, the catheter was withdrawn to straddle the mitral valve. **C:** Partial filling of the balloon. **D:** Complete filling of the Inoue balloon across the mitral valve. This dilation reduced the mitral valve gradient from 18 to 2 mm Hg.
Immediate Results

Immediate results of mitral valvuloplasty are assessed by a combination of Doppler echocardiographic measurements and hemodynamics. Repeat evaluation of mitral valve area during the procedure by hemodynamic measurements can be performed with a reasonable degree of accuracy in catheterization laboratories equipped with computer analysis systems. There is some inaccuracy to the Gorlin formula in the presence of an atrial shunt or mitral regurgitation. Nevertheless, in successful procedures the mitral valve gradient will be observed to be substantially reduced.

Figure 26.4 illustrates a typical reduction in left atrial pressure and transmitral gradient immediately after balloon mitral valvuloplasty. The mitral valve orifice area is usually increased by more than 1 cm²/m² body surface area. By echocardiographic assessment in the laboratory, particularly planimetry of the mitral valve orifice image in the two-dimensional echocardiogram short-axis view, another confirmation of improvement of mitral valve orifice area can be measured. The accuracy of Doppler measurements during valvuloplasty can be variable, but color Doppler assessment is the method of choice for sequential evaluation of the degree of mitral regurgitation. The new appearance of mitral regurgitation or an increase greater than 1 grade on the 0 to 4 classification of preexisting mitral regurgitation in general signals an end point of the procedure. Additionally, if the mitral valve area has increased to more than 2 cm², or if there has been a complete opening of at least one commissure on echocardiography, the procedure has been completed successfully. The clinical circumstances and anatomic factors of each individual patient must be considered carefully in determining the end point of the procedure.

FIG. 26.4.

Pressure tracings in a patient with severe mitral stenosis, showing simultaneous left atrial (LA) and left ventricular (LV) pressures before (A) and after (B) balloon mitral valvuloplasty.

Long-term Hemodynamic Results

Numerous studies have demonstrated the effectiveness of balloon valvuloplasty in increasing mitral valve area. There is almost always a near-doubling of effective mitral valve area, a decrease in left atrial pressure, and usually a slight increase in cardiac output. Over time, there is a gradual decrease in pulmonary artery pressure and pulmonary vascular resistance. Longer-term follow-up analyses of up to 5 years are now available. These studies show quite satisfactory results for this technique. Table 26.2 looks at the 4- and 5-year follow-up results in patients from four series. In a fifth series, the National Heart, Lung, and Blood Institute (NHLBI) Balloon Valvuloplasty Registry reported multicenter results in 736 patients older than 18 years of age who were monitored for 4 years. The actuarial survival rates at 1, 2, 3, and 4 years were 93%, 90%, 87%, and 84%, respectively. The rates of event-free survival (freedom from death, mitral valve surgery, or repeat balloon valvuloplasty) at 1, 2, 3, and 4 years were 80%, 71%, 66%, and 62%, respectively. Multivariate predictions of mortality were New York Heart Association (NYHA) functional class IV, echocardiographic mitral valve score greater than 12, postprocedure systolic pulmonary artery pressure greater than 40 mm Hg, and left ventricular end-diastolic pressure greater than 15 mm Hg.

Complications

In skilled hands, the failure rate of the procedure should be less than 5%. Failure usually results from the inability to puncture the interatrial septum safely because of anatomic difficulties or, in some cases, to position the balloon catheter successfully across the mitral valve. The procedural mortality rate varies from 0% to 3% in most series. Hemopericardium related to transseptal catheterization, atrial puncture, or, rarely, apex perforation by balloon or wires varies in incidence from 0.5% to 10%. Systemic embolization has been encountered in 0.5% to 5% of cases. These complications diminish with increasing operator experience.

Severe mitral regurgitation is uncommon, ranging in incidence from 2% to 9%, and is usually related to noncommissural leaflet tearing. It may also be associated with chordal rupture. Usually, in these circumstances, one or both of the mitral commissures were too tightly fused to be split successfully by the balloon, and the leaflets tore.
along noncomissural lines. Most cases of severe mitral regurgitation occur in patients with unfavorable mitral valve anatomy. Usually, even severe mitral regurgitation is well tolerated for a time by the patient, but in general elective surgical replacement of the valve is necessary because of the severity of the underlying valvular and subvalvular disease (29).

**Comparison of Percutaneous Balloon Mitral Valvuloplasty and Surgery**

Two prospective, randomized studies of young patients in India and South Africa compared the clinical and hemodynamic results of percutaneous balloon valvuloplasty with those of closed surgical valvotomy (30),(31). The valvuloplasty results compared favorably with those obtained surgically. In one study, better functional and hemodynamic results occurred in the patients treated with percutaneous balloon valvuloplasty (31). An additional trial looked at 60 patients who were randomly assigned prospectively to percutaneous balloon valvuloplasty or open surgical commissurotomy (32). Initial mitral valve area increased from a mean of 0.9 to 2.1 cm\(^2\) in the balloon valvuloplasty group and from 0.9 to 2.0 cm\(^2\) in the surgical patients. However, after 3 years the patients treated with balloon valvuloplasty had a higher average mitral valve area (2.4 vs. 1.8 cm\(^2\)) and a greater likelihood of NYHA class I status (72% vs. 57%).

Open surgical commissurotomy, closed surgical commissurotomy, and percutaneous balloon valvuloplasty were compared in a trial of 90 patients (33). Short- and long-term (7-year) outcomes were not as good with closed surgical commissurotomy. The increase in mitral valve area was greater after percutaneous balloon valvuloplasty (from 0.9 to 2.2 cm\(^2\)) and open commissurotomy (from 0.9 to 2.0 cm\(^2\)) than after closed commissurotomy (from 0.6 to 1.6 cm\(^2\)). Early and late mortality and thromboembolism were similar among the three groups. At 7 years follow-up, NYHA class I was present in 87%, 90%, and 33% of patients for balloon valvuloplasty, open commissurotomy, and closed commissurotomy, respectively, and freedom from repeat intervention was 90%, 93%, and 53% respectively.

**PULMONIC VALVULOPLASTY**

Pulmonary valve stenosis is a relatively common congenital defect. Mild to moderate pulmonary stenosis in children has generally a benign clinical course, with a high rate of survival into adulthood. Therefore, the adult interventional cardiologist will encounter previously undetected and untreated patients who are candidates for balloon valvuloplasty.

**Pathophysiology**

The typical patient with valvular pulmonic stenosis has a trileaflet valve, with varying degrees of fibrous thickening and fusion of the commissures. These restricted valve leaflets have a characteristic dome-shaped, or conical, appearance during systole on angiography or echocardiography. Bicuspid pulmonic valves are uncommon (less than 20%), and heavy calcification of the stenotic valve is rare. These features make the stenotic pulmonary valve well suited for balloon valvuloplasty. Other forms of congenital pulmonic stenosis not well suited for valvuloplasty include dysplastic valves (Noonan's syndrome) and primary fibromuscular subvalvular narrowing.

Balloon valvuloplasty evolved from a long surgical experience with mechanical valve dilatation, valvulotomies (Brock procedure), bougies, and finally, under cardiopulmonary bypass, direct incision of fused pulmonic valve commissures. Since the initial balloon valvuloplasty of the pulmonary valve in 1979 with an angiographic balloon catheter, larger-diameter, longer-length polyethylene balloon catheters have been developed to allow this procedure to be performed successfully and safely in children and adults (34),(35). The proposed mechanism for successful balloon valvuloplasty is predominantly mechanical separation of congenitally fused commissures. Also, there appears to be in some patients minor tearing of valve leaflets, and occasionally avulsion of the cusps.

Patients with moderate pulmonic stenosis and a gradient of 50 to 100 mm Hg who have symptoms of exercise intolerance will probably benefit from balloon valvuloplasty. Patients with severe pulmonic stenosis, defined as a gradient greater than 100 mm Hg, may benefit from balloon valvuloplasty even in the absence of symptoms, because of the significant afterload that the obstructive pulmonary valve places on the right ventricle (36).

**Technique**
After careful selection of a symptomatic patient with a moderate or severe gradient across the pulmonary valve by echocardiographic and Doppler evaluation, successful pulmonary valvuloplasty begins with a careful right-sided heart catheterization to document the pulmonary valve gradient and to exclude a significant supravalvular or subvalvular component. We usually place a 5F sheath in the left femoral artery for pressure monitoring and perform the procedure from the right femoral vein after the introduction of an 8F sheath. A right ventricular angiogram is done in the anteroposterior and lateral projections to determine the exact location of the pulmonary valve and to allow sizing of the pulmonary annulus. For sizing, we usually use external markers on the chest at the level of the pulmonary valve, such as a nickel taped to the chest, and we use either a pigtail catheter with tantalum markers spaced 1 cm apart or a balloon angiographic catheter whose inflated balloon is approximately 1 cm in diameter. We usually employ the dual-balloon technique in adult patients, initially selecting balloon sizes approximating the diameter of the annulus and then increasing the size, if necessary, to abolish the gradient. It is often necessary to oversize the calculated annulus diameter by as much as 25%.

After angiographic localization of the pulmonary valve, the valve is crossed with a dual-lumen balloon flotation catheter. This catheter is useful for measuring the gradient from its end-hole lumen, as well as its side-hole lumen, 5 cm from the tip. Pressure gradients can be measured by this catheter before and after balloon dilatation. Both lumens are passed distally into the pulmonary artery, and two 0.038-inch, heavy-duty exchange-length guidewires are passed into the distal pulmonary artery, one through the end-hole lumen and one through the side-hole lumen. The catheter is then removed, leaving the wires in place in the pulmonary artery exiting the body through the femoral vein. The pulmonary valvuloplasty balloons, having been previously purged of air and filled with diluted radiographic contrast, are then inserted one after the other in tandem into the femoral vein. They are positioned one at a time with the aid of both the external markers and the balloon markers so that the midportion of the valvuloplasty balloon is straddling the pulmonary valve. When both balloon catheters are in place, they are rapidly and simultaneously filled with the dilute radiographic contrast solution. The balloons are filled until the “waist” is seen to disappear on fluoroscopy. The balloon catheters are emptied and then withdrawn from the body sequentially over the two heavy-duty “J” wires. A 12F sheath is introduced into the femoral vein over the guidewires, and the dual-lumen catheter is reintroduced through the sheath and positioned across the pulmonary valve over one of the wires. That guidewire is then removed, and a careful determination is made of the residual valvular gradient, if any. In a successful balloon pulmonic valvuloplasty, the valvular gradient is almost always abolished, or nearly so. However, on occasion the operator encounters a previously undetected subvalvular gradient after the valvular gradient has been eliminated. This subvalvular gradient usually diminishes and disappears over the ensuing weeks, with regression of the right ventricular hypertrophy. Repeat dilatation of the pulmonary valve should be performed with larger balloons only when there is a persistent and significant valvular gradient. Repeat dilatation of the pulmonary valve for a subvalvular gradient is contraindicated.

Clinical Results and Complications

The impressive acute and long-term results of this procedure in adolescents and adults make balloon valvuloplasty the treatment of choice for valvular pulmonic stenosis. A pooled analysis involving 784 patients of all ages showed that clinical success was achieved with balloon valvuloplasty in 98% of patients (37). Procedural mortality was less than 0.5%, and the average peak valve gradient fell from 85 to 33 mm Hg. Several series have looked at the long-term efficacy of balloon valvuloplasty. Chen and colleagues reported on a series of 53 adolescent and adult patients, ages 13 to 55 years, treated between 1985 and 1995 (38). The systolic pressure gradient across the pulmonary valve fell from 91 ± 46 to 38 ± 32 mm Hg after the procedure. On late follow-up (average, 7 years), the gradient had fallen further. Seven of 53 patients developed pulmonary insufficiency immediately after the valvuloplasty, but none had this complication at late follow-up evaluation.

Procedural complications are rare during the procedure, and at our institution pulmonic valvuloplasty is usually planned as an outpatient procedure. Patients may have arrhythmias and occasional hypotension during balloon inflation. Transient right bundle branch block has been observed. Despite the use of large balloon catheters, bleeding and vascular complications are very infrequent because this procedure is done through the femoral vein.

**BALLOON AORTIC VALVULOPLASTY**
Dilatation of the stenotic aortic valve, whether by surgical technique or percutaneous balloon valvuloplasty, has not enjoyed the same level of success as therapy for the pulmonic and mitral valves. Surgical mechanical dilatation of the stenotic adult aortic valve has been attempted since the 1950s, but the use of various valvulotomies has failed to provide a significant solution for the problem of calcific aortic stenosis and has been abandoned in favor of aortic valve replacement. Open surgical valvotomy remains an option for infants and children with critical aortic stenosis, in whom it is desirable to postpone a definitive aortic valve replacement.

Noncalcific Aortic Stenosis

Percutaneous balloon aortic valvuloplasty was first performed in children and young adults by Lababidi in 1984 (39). Balloon dilatation resulted in a significant decrease in peak aortic valve gradient. Considerable experience exists with balloon valvuloplasty in children and adolescents with noncalcified congenital stenotic aortic valves, with excellent short-term and satisfactory long-term results (40–42). The predominantly fibrotic nature of these congenitally stenotic valves makes them well suited for balloon valvuloplasty. The procedure is effective 80% to 90% of the time, with a mortality rate of approximately 0.7%. Survival at 8 years has been reported to be 95%, with the need for repeat intervention 25% at 4 years and 50% at 8 years (43). There may be a role for balloon valvuloplasty in the young adult without significant valve calcification. A study of young adults ages 17 to 40 years (mean, 23 years) with congenital aortic stenosis showed that balloon aortic valvuloplasty produced a significant reduction in the gradient across the aortic valve and an increase in the aortic valve area (44). In this series there were no deaths or embolic cerebrovascular events. Intermediate follow-up at 38 months showed that 50% of patients required no further intervention. The absence of significant valve calcification is an important predictor of a good short- and long-term result.

Calcific Aortic Stenosis

The more typical patient encountered by the adult cardiologist is the elderly patient with acquired calcific aortic stenosis. Although experience with successful balloon valvuloplasty for this condition dates back to 1986 (45), (46), the procedure has a very limited role at present because of the unpredictability of the initial benefit and the very high rate of recurrence or “restenosis.” Virtually all symptomatic patients with calcific aortic stenosis should undergo aortic valve replacement as the treatment of choice. There are, however, certain settings where balloon valvuloplasty may play an important palliative role in patients who are not candidates for immediate valve replacement. These are listed in Table 26.3. Balloon aortic valvuloplasty is useful in the patient presenting with cardiogenic shock due to aortic stenosis and can serve as a successful bridge to definitive surgery in these hemodynamically unstable patients (47). It may also be used for palliation in patients with serious comorbid conditions. The technique is also used in patients with critical aortic stenosis who require urgent noncardiac surgery if it is thought that more conservative medical therapy presents excessive risk.

Mechanism of Improved Aortic Orifice Area

Postmortem and intraoperative dilatations have shown how balloon aortic valvuloplasty improves calcific degenerative aortic stenosis in the adult (48). Balloon dilatation increases the mobility of leaflets, thus enlarging the aortic valve orifice. The mechanism of dilatation appears to be predominantly fracturing of the calcific aortic valve nodules (48). In addition, in some elderly patients there may be separation of postinflammatory fused commissures.

Technique

The retrograde aortic technique for balloon aortic valvuloplasty is the one most commonly used. In the typical patient we use both femoral arteries. A 5F pigtail catheter is inserted from the left femoral artery and positioned in the ascending aorta for pressure monitoring and gradient determination. Right-sided heart catheterization is done from the left femoral vein. A balloon flotation thermodilution catheter is placed in the pulmonary artery and remains there throughout the procedure. Cardiac output is determined by both Fick and thermodilution techniques. Using the right femoral artery, an 8F sheath is introduced, through which left-sided heart catheterization is performed. A 0.038-inch straight-tip guidewire is used to cross the aortic valve. A pigtail catheter is placed in the left ventricle, the aortic valve gradient is measured, and the aortic valve area is determined by the Gorlin formula. All patients are
heparinized before any attempt is made to cross the aortic valve. After these prevalvuloplasty measurements, a heavy-duty 0.038-inch exchange-length (300-cm) guidewire (Schneider-Boston Scientific, Maple Grove, MN) with a double curve placed at its tip is inserted into the left ventricle. The previously placed pigtail catheter is removed, and a 12F sheath is placed over this wire into the femoral artery. It is important that the groin be anesthetized adequately to avoid discomfort and possible vagal reaction during sheath exchange. Through the sheath the previously prepared dilatation balloon is advanced over the guidewire. To keep its profile minimal, the balloon (purged of air) is kept completely deflated by constant negative pressure from a syringe and is introduced with a counterclockwise rotation.

**FIG. 26.5.**

Anteroposterior projection shows passage of the deflated aortic valvuloplasty balloon across a stenotic aortic valve. Balloon markers are positioned so that the balloon straddles the calcified aortic valve.

Under fluoroscopy, using two operators, the heavy-duty guidewire is kept in the left ventricle as the balloon valvuloplasty catheter is advanced and positioned to straddle the aortic valve. Using the proximal and distal markers of the balloon, the operator attempts to place the middle of the balloon at the level of the calcific aortic valve. Figure 26.5 illustrates the unfilled balloon straddling the aortic valve.

In most normal-sized adults with an adequate aortic valve annulus, we begin with a 20-mm diameter, 5.5-cm long balloon. In very small or frail patients, the operator can start with an 18-mm balloon or (very rarely) a 15-mm balloon. The balloon is filled with diluted contrast medium using either a very large syringe or an angioplasty end-deflator-type device. Care must be taken to maintain balloon position within the valve orifice to achieve an effective dilatation. The balloon catheter may tend to jump either forward or backward with the force of ventricular systole. To achieve a stable balloon position, we initially fill the balloon slowly, while one operator fixes the balloon in a stable position. Once a good position is achieved, the balloon is filled rapidly to its maximum diameter. We constantly monitor the electrocardiogram for arrhythmia and ischemia. The aortic pressure is also monitored continuously. If tolerated, the balloon is left filled for 15 to 20 seconds. The balloon is then emptied and withdrawn into the aorta, keeping the guidewire in the left ventricle. If significant hypotension, ischemia, or sustained ventricular tachycardia occurs, the balloon is emptied immediately. A period of stabilization to allow blood pressure and electrocardiographic changes to return to baseline should be allowed before further dilatations. It is often necessary to exert considerable force on these balloons to expand them fully and relieve the “waist” caused by the stenotic aortic valve.

**FIG. 26.6.**

Balloon aortic valvuloplasty using the double-balloon technique in a 94-year-old woman who presented with syncope and failure. Full inflation of two 18-mm diameter, 5.5-cm SciMed balloons across the stenotic aortic valve is shown.

After several dilatations with a single balloon or after balloon rupture (a frequent occurrence), the balloon is withdrawn through the sheath, leaving the exchange-length, heavy-duty wire in place. It is frequently necessary to remove the 12F sheath along with the deflated valvuloplasty balloon, because the valvuloplasty balloons do not always rewrap adequately to allow removal through the sheath. The pigtail catheter is then reintroduced over the guidewire back into the left ventricle, and measurements of the pressure gradient and cardiac output are repeated. The aortic valve area is calculated. Our usual goal is to increase the aortic valve area by more than 100% and to achieve a valve area of at least 1 cm². If a desirable result has not been achieved, we change to a 23-mm diameter balloon and repeat the procedure. If an adequate result is not achieved with the single 23-mm balloon, we then employ a dual-balloon technique, using a pair of 15- or 18-mm balloons if aortic annulus size permits. For this technique the other femoral artery is used to access the aorta and left ventricle. Pressure is monitored through the side-arm of the 12F sheath during the procedure. Figure 26.6 illustrates the dual balloon technique, and Fig. 26.7 shows the progressive reduction in gradient with single, followed by dual, balloon valvuloplasty. After a successful procedure, patients are placed in a recovery area or in the coronary care unit for continued observation. The femoral artery sheaths are removed after the coagulation parameters are in the normal range, and hemostasis is maintained either by manual pressure or a fem-stop device.
Balloon aortic valvuloplasty in an elderly patient with severe calcific aortic stenosis. A: Baseline pressure gradient across the stenotic aortic valve measured with one catheter in the left ventricle (LV) and a separate pigtail catheter in the ascending aorta (A-AORTA). There is a 58 mm Hg mean gradient and an 80 mm Hg peak-to-peak gradient across the valve. B: Reduction in the aortic valve gradient after a series of progressive single-balloon dilatations of the aortic valve. C: Marked reduction in aortic valve gradient after dual-balloon valvuloplasty.

Clinical Results and Complications

In the large Mansfield balloon aortic valve registry, data were collected from 27 clinical centers across the United States and Europe from 6,742 patients with calcific aortic stenosis undergoing balloon aortic valvuloplasty between 1986 and 1987 (49). Balloon aortic valvuloplasty resulted in an increase in aortic valve area from 0.5 ± 0.18 to 0.81 ± 0.18 cm², and a decrease in mean aortic valve pressure gradient from 60 ± 24 to 30 ± 14 mm Hg. There was also an accompanying increase in cardiac output, from 3.86 ± 0.55 to 4.01 ± 0.51 L/min. Complications were experienced in 22.6% of patients, including a procedural death rate of 4.9%, death within 7 days 2.6%, emboli 2.2%, ventricular perforation 1.4%, and emergency aortic valve replacement 1.2%. The most common complication was local vascular injury, which required surgical repair in 5.7% of patients (50). The NHLBI balloon valvuloplasty registry enrolled patients from 1987 to 1989 at 24 clinical centers (51). Similar results were obtained, with balloon aortic valvuloplasty increasing aortic valve area from 0.5 ± 0.2 to 0.8 ± 0.5 cm², decreasing aortic valve pressure gradient from 57 ± 30 to 29 ± 13 mm Hg, and increasing cardiac output from 3.9 ± 1.2 to 4.1 ± 1.2 L/min. Complications included procedural death (2%), cardiac arrest (5%), emergency aortic valve replacement (1%), left ventricular perforation (2%), and embolic stroke and systemic emboli (1%).

The use of newer balloons with smaller deflated profiles and the use of large vascular sheaths may be reducing the incidence of vascular trauma. Ventricular arrhythmias and left bundle branch block are very commonly induced during the procedure; however, both are usually transient.

Long-Term Results

Restenosis with recurrent symptoms is very common in the first year after balloon valvuloplasty in the adult with calcific aortic stenosis (52–54). In the NHLBI-sponsored balloon valvuloplasty registry, the survival rates at 1, 2, and 3 years were 55%, 35%, and 23%, respectively, in the 674 patients undergoing balloon aortic valvuloplasty (51). The 1-year survival rate in the Mansfield registry of 492 patients was 64%, with an event-free survival rate of 43% (49),(55). Therefore, it must be emphasized that, when at all feasible, definitive aortic valve replacement is the technique of choice for managing the adult patient with severe calcific aortic stenosis.

Short-term clinical improvements associated with balloon aortic valvuloplasty may be accompanied by improvement in systolic and diastolic left ventricular function in some patients (56). Patients with significantly depressed left ventricular function undergoing this procedure have a very poor long-term prognosis (57). In the patient with cardiogenic shock who has been stabilized with successful balloon aortic valvuloplasty, cardiac surgery with definitive aortic valve replacement should be undertaken soon after the patient’s condition stabilizes (47),(58).