

# Percutaneous Balloon Valvuloplasty

*Thomas M. Bashore*

Charles Dotter is credited with noting that the stenotic severity of a high-grade iliac lesion was lessened when a diagnostic catheter was passed through it. Early vascular efforts used progressively larger catheters to open the lesions by blunt dilatation. Eventually, this approach using progressively larger bougies was replaced by the use of elastic balloon-tipped catheters, first for peripheral vascular disease, then for coronary angioplasty. Reports from the National Heart, Lung, and Blood Institute (NHLBI) registry, the Mansfield balloon catheter registry, and large institutional experiences subsequently shaped the development of percutaneous balloon procedures for stenotic valvular lesions.

As technology advances resulted in more effective percutaneous approaches to the treatment of valvular stenosis, the terminology used to describe these procedures evolved as well. The term “commissurotomy” originated from the surgical procedure developed for commissural mitral valve stenosis (see chapter 34), and some thought valvuloplasty should be reserved for surgical procedures that more directly altered the valvular structure. As an initial compromise, the NHLBI registry suggested that the term “valvotomy” be used for aortic and pulmonic procedures and commissurotomy for mitral procedures. These terms are often used in the older literature. In recent years, “valvuloplasty” has become the term of choice to describe procedures in which stenotic valves are opened by balloon dilatation. This term, analogous to balloon angioplasty, is established in the cardiology community and is used in this chapter.

## **PULMONARY VALVE STENOSIS**

### **Pathophysiology**

Pulmonary valve stenosis results from fusion of the valve cusps during mid to late fetal development. The most common form of isolated right ventricular (RV) obstruction, pulmonary valvular stenosis occurs in approximately 7% of individuals with congenital heart disease (see also chapters 44 and 45). Pulmonary valve stenosis may be associated with significant RV hypertrophy and infundibular narrowing. The fusion of the valvular cusps produces a classic systolic “doming” appearance angiographically (Fig. 33-1). Tissue pads within the valve sinuses

may exist and result in a thickened, rigid valve that is considered dysplastic. Excessive thickening in dysplastic valves usually renders the valve unsuitable for percutaneous valvuloplasty, although attempts have occasionally been successful. The dysplastic form is common in Noonan’s syndrome. The greater the severity of congenital pulmonary valvular stenosis, the more likely the RV outflow tract will also be narrowed and the lesion will resemble pulmonary valve atresia. Balloon valvuloplasty is contraindicated in individuals with annular hypoplasia. Fortunately, in adults, the most common form of pulmonary valve stenosis results from commissural fusion, making this lesion amenable to percutaneous balloon methods.

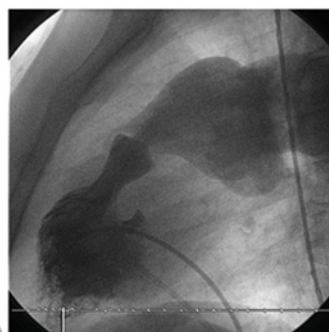
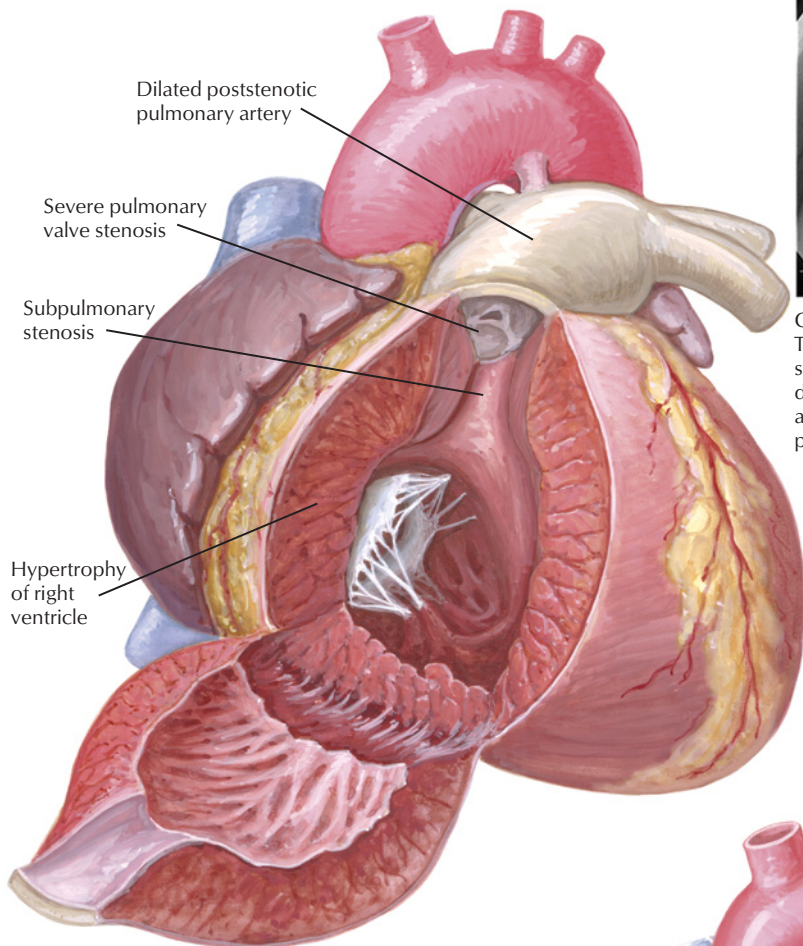
Figure 33-2 demonstrates the gradient between the right ventricle and the pulmonary artery before and after successful percutaneous balloon valvuloplasty. The RV outflow track may have considerable subpulmonic stenosis, which may be masked when valvular obstruction is present. The sudden removal of the valvular stenosis after valvuloplasty may result in acute decompensation from marked RV infundibular obstruction, sometimes called the “suicide RV.” Fluid loading, calcium channel blockers, and  $\beta$ -blockers can be used for emergent treatment. After pulmonary valvuloplasty, the subpulmonic hypertrophy may regress considerably over the next several months.

### **Indications**

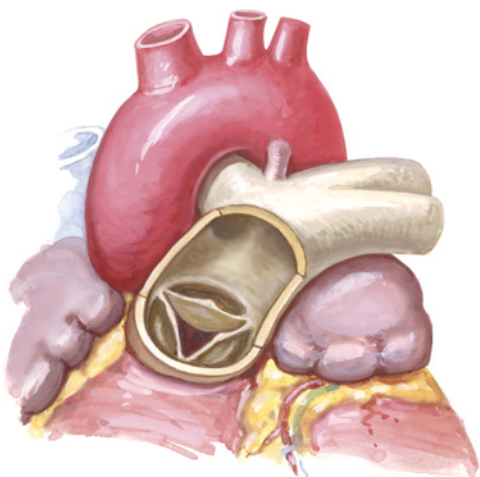
Valvular regurgitation is generally graded from 1+ (mild) to 4+ (severe). In patients with less

Figure 33-1

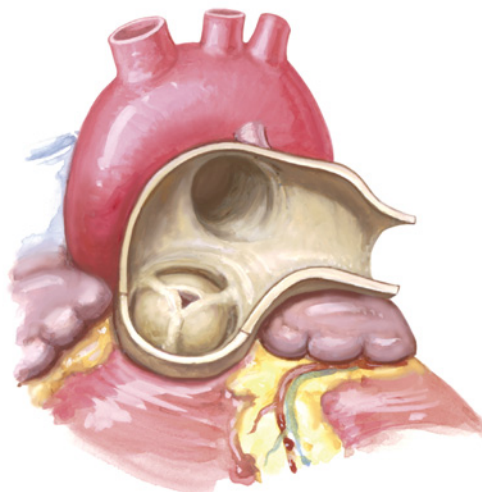
Pulmonary Stenosis



Classic pulmonary valvular stenosis. The figure reveals the doming stenotic pulmonary valve evident during right ventricular angiography. Note the dilated poststenotic pulmonary artery.



Open normal pulmonary valve

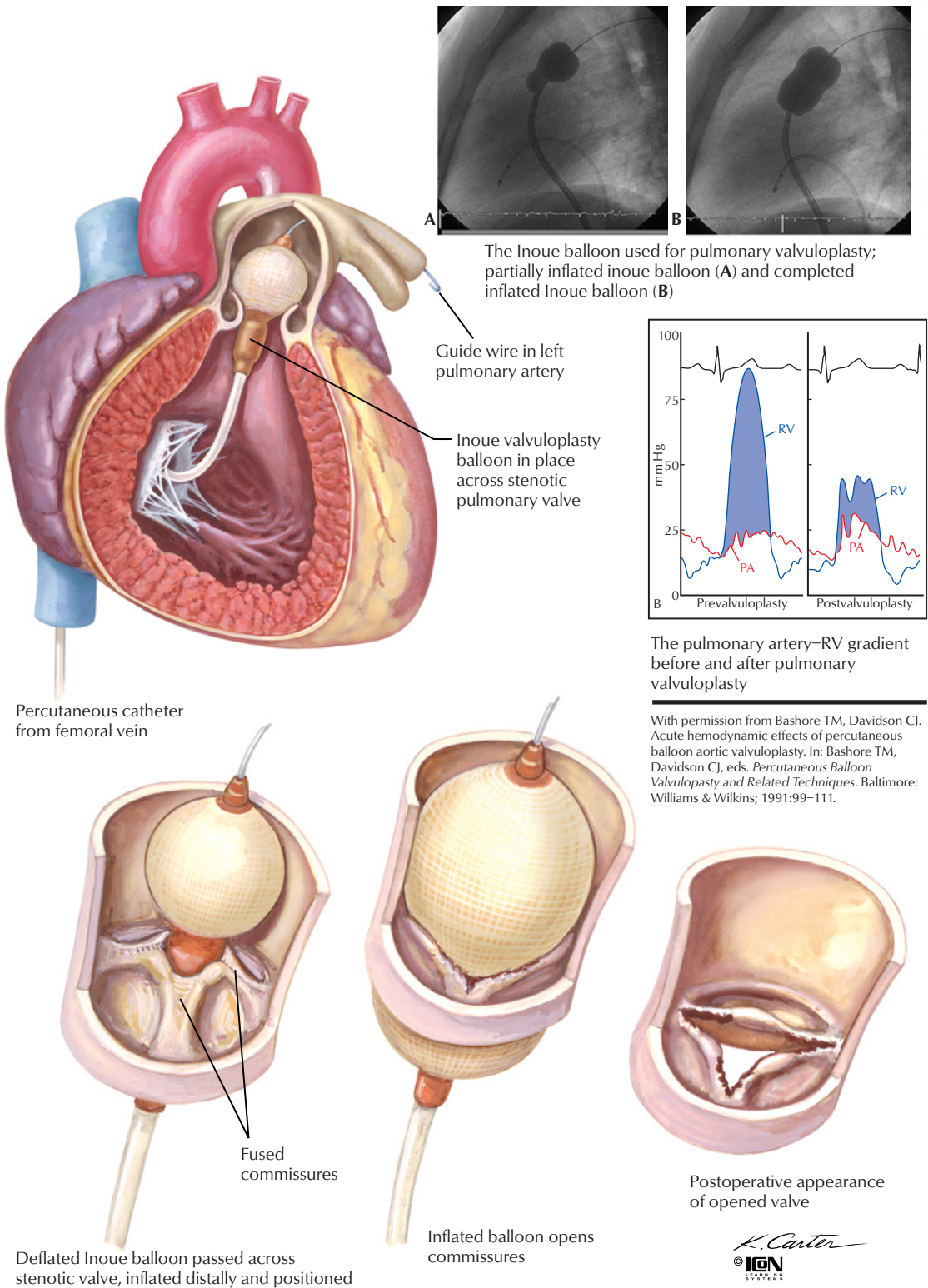


Open stenotic pulmonary valve with fused commissures creating the classic domed shape

*K. Carter*  
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**Figure 33-2**

**Pulmonary Balloon Valvuloplasty**



The pulmonary artery–RV gradient before and after pulmonary valvuloplasty

With permission from Bashore TM, Davidson CJ. Acute hemodynamic effects of percutaneous balloon aortic valvuloplasty. In: Bashore TM, Davidson CJ, eds. *Percutaneous Balloon Valvuloplasty and Related Techniques*. Baltimore: Williams & Wilkins; 1991:99–111.



Inoue Balloon Catheter, Toray Industries, Inc., Tokyo, Japan.

than 2+ pulmonic insufficiency and a doming pulmonic valve, a peak pulmonary valve gradient of 50 mm Hg at cardiac catheterization is sufficient to warrant balloon valvuloplasty even without symptoms. Any evidence of RV dysfunction or associated RV failure and tricuspid regurgitation should prompt intervention. For the reasons described previously, procedural success is much lower in patients with pulmonary valve dysplasia. Percutaneous balloon valvuloplasty of the pulmonary valve has also been reported to be of some limited success in patients with carcinoid involvement of the pulmonic valve.

### Technique

Before the procedure, RV angiography in the cranial right anterior oblique and straight lateral views is performed. Pulmonary angiography assesses preprocedural pulmonic insufficiency. Severe pulmonic insufficiency is a contraindication to valvuloplasty; severe insufficiency as a result of the procedure represents an adverse outcome. Baseline annular size is determined by echocardiography, magnetic resonance imaging, or contrast angiography. In the cardiac catheterization laboratory, a catheter (with radiopaque markers a known distance apart) may be used for angiography at the valve level to determine appropriate balloon size. Quantitative angiographic methods may be similarly applied.

The dilating balloon or balloons are percutaneously inserted into the femoral vein without a sheath. The maximum inflation of the balloon(s) should be equal to 1.2 to 1.4 times the estimated annular size (Fig. 33-2). In contrast to the aortic valve (see Aortic Valve Stenosis section), the pulmonary artery is elastic and often requires oversizing for adequate results. The goal of the procedure is a final peak valvular gradient less than 30 mm Hg. Recurrence rates are much lower if that threshold is reached. A single balloon, often 23 mm in diameter in adults, may be used, although two balloons side by side may be necessary in patients with a large annulus. In some laboratories, trefoil or bifoil balloon catheters are available and preferred. The Inoue mitral valvuloplasty balloon has increasingly been used for pulmonary valvuloplasty because of its stability during inflation.

Careful measurement of postprocedural gradients allows differentiation of infundibular stenosis from residual valvular stenosis. Postprocedural RV and pulmonary artery angiography help assess the severity of pulmonic insufficiency that has developed as a result of the procedure and also can address the presence and significance of infundibular stenosis.

### Short-Term Results and Complications

Numerous groups have reported excellent short-term results in children and adults, as exemplified by a report of 66 infants and children in whom the peak gradient across the pulmonic valve fell from  $92 \pm 43$  mm Hg to  $29 \pm 20$  mm Hg with no change in cardiac output. The NHLBI adult registry included 37 adult patients, the procedure was completed in 97%, and the average peak gradient decreased from 46 to 18 mm Hg. Larger balloon sizes, up to 30 to 50% larger than the annulus, resulted in greater reductions in the valvular gradient without increasing complications.

Minimal complications in the acute setting include vagal symptoms and ventricular ectopy from catheters in the right ventricle. Pulmonary edema, presumably from increasing pulmonary flow to previously underperfused lungs, perforation of a cardiac chamber, high-grade atrioventricular nodal block, and transient RV outflow obstruction have also been reported. Pulmonary valve insufficiency occurs in about two thirds of the patients after the procedure, but it is rarely clinically significant.

### Long-Term Results

Long-term data are available for up to 10 years after percutaneous balloon valvuloplasty of the pulmonary valve. In one representative study, 62 children undergoing this procedure, with an average balloon-to-pulmonary annulus ratio of 1.4, were followed up for a mean of  $6.4 \pm 3.4$  years. Persistent pulmonary valve insufficiency was found in 39% of the patients, there was evidence of a progressive resolution of infundibular hypertrophy, and the restenosis ( $>35$  mm Hg gradient) rate was only 4.8%. Restenosis was more common in patients with dysplastic valves. If restenosis occurred, repeat valvuloplasty appeared to be effective in patients without dysplastic pulmonary valves.

These data compare quite favorably with the outcomes of surgical valvotomy. One large study of surgical valvotomy in children reported a surgical mortality rate of 3%, with poor surgical results (residual gradient  $>50$  mm Hg) in 4%. Restenosis rates after surgery were 14 to 33% at up to 34 months of follow-up. Thus, percutaneous balloon valvuloplasty for valvular pulmonary stenosis appears to be the treatment of choice and provides excellent short- and long-term relief from pulmonary valvular obstruction.

### AORTIC VALVE STENOSIS

#### Pathophysiology

The normal aortic valve has thin, flexible cusps composed of three tissue layers sandwiched between layers of endothelium on both sides of the valve. The layers include a fibrosa with collagen fibers oriented parallel to the leaflet that support the major leaflet, a ventricularis layer composed of elastic fibers oriented perpendicularly to the leaflet edge that provide flexibility, and a spongiosa layer of loose connective tissue in the basal third of each leaflet.

Congenitally deformed aortic valves can generally be described as either unicuspid or bicuspid. Unicuspid valves are inherently stenotic at birth and cause symptoms early in life. Unicuspid aortic valves account for about 10% of all cases of isolated aortic valve stenosis in adulthood, whereas bicuspid aortic valves account for about 60% of isolated aortic valve stenosis in patients aged 15 to 65 years of age. Bicuspid aortic valves generally have two cusps of nearly equal size with little commissural fusion, but with a false commissure (raphe) present in one cusp. Over time, progressive valvular fibrosis and calcium deposition occurs, worsening the functional stenosis. Some commissural fusion may occur, but the major limitation is usually valvular rigidity from calcium buildup and scarring.

Aortic valve stenosis in elderly persons generally involves a trileaflet valve and likely represents a continuum, from benign aortic valvular sclerosis to severe aortic valvular stenosis. The prevalence of aortic valve sclerosis has been reported to be 25% in individuals older than 65 years of age, with severe aortic valve stenosis evident in 1 to 2% of the population. There is evidence that the mechanism of calcific aortic

valve stenosis in the elderly is related to atherosclerosis. Little commissural fusion exists; large accretions of calcium can be present in the sinuses of Valsalva. The leaflets gradually lose their flexibility due to these calcium deposits. In calcific aortic valve stenosis, the minimal reduction in the gradient that can be obtained by balloon procedures has generally been attributed to cracks in the calcific nodules, cuspal tears, and aortic wall expansion (Fig. 33-3).

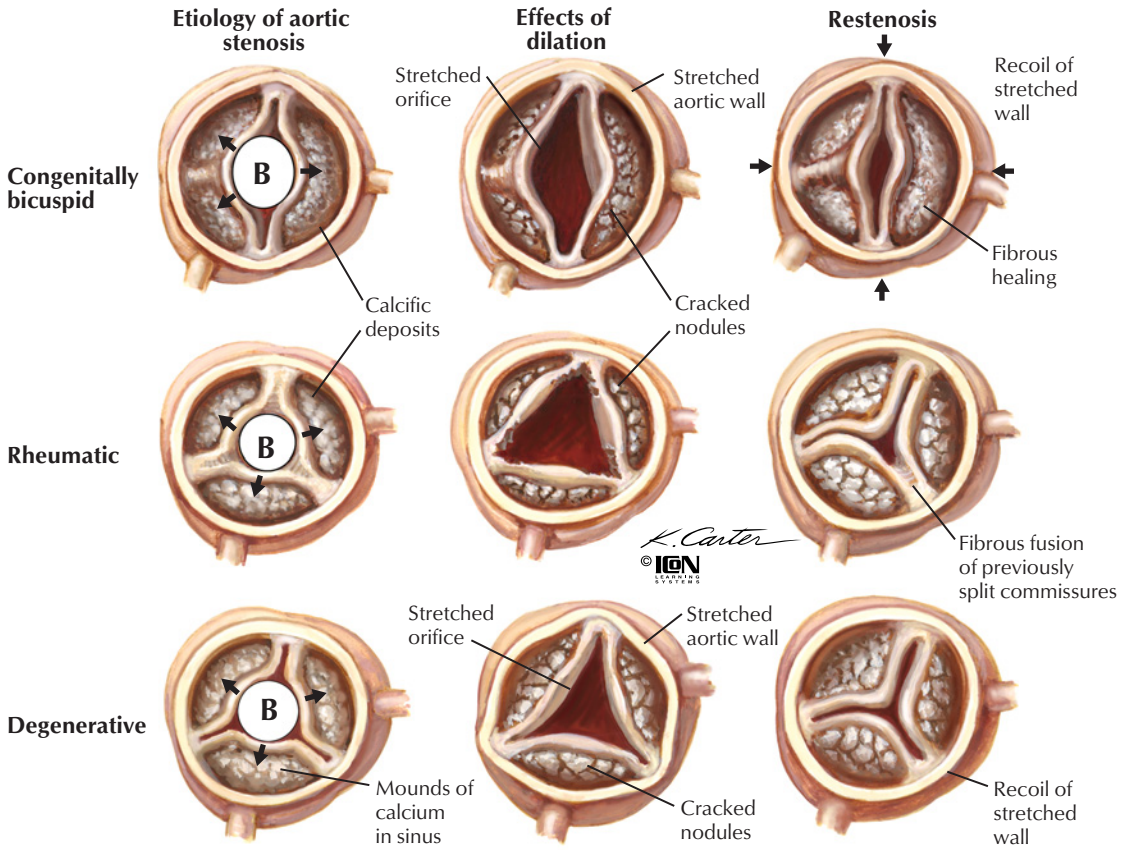
When left ventricular (LV) outflow is obstructed at the valvular level, a gradient develops between the left ventricle and the aorta (Fig. 33-3). The relationship between the gradient and the aortic valve area (AVA) is complex, however, and depends on the severity of the lesion as measured by the AVA and on the cardiac output or the aortic flow. After aortic valvuloplasty, aortic flow may increase because of an improvement in the cardiac output or the development of aortic insufficiency. Either result could increase the gradient, even if the actual AVA increases. Alternatively, the cardiac output may fall and the gradient may appear lower even if the AVA has increased. Thus, the short-term postprocedural valvular gradient change may not always reflect the actual change in the AVA.

Using just the change in the AVA can be problematic for other reasons. For instance, if the baseline AVA is severe, an improvement in the AVA of  $0.3 \text{ cm}^2$  from baseline has a dramatic effect on the peak LV systolic pressure (e.g., when the AVA increases from  $0.5$  to  $0.8 \text{ cm}^2$ ), but if the baseline AVA is less severe, the same incremental change may have much less consequence (e.g., when the AVA increases from  $0.8$  to  $1.1 \text{ cm}^2$ ). Hence, either an improvement in the gradient, or an improvement in both the gradient and the final valve area can be used to define a successful result (i.e., a final valve gradient of  $<50$  mm Hg and/or a 50% improvement in the AVA).

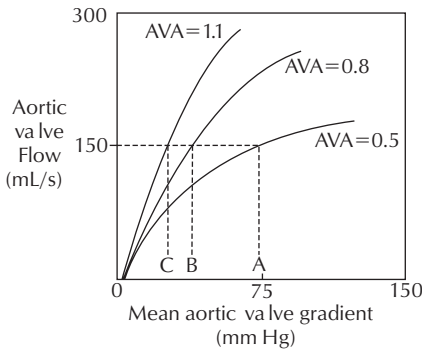
#### Indications

The decision whether to intervene in aortic valve stenosis usually depends on the presence of symptoms of congestion, angina, or exertional syncope, and an assessment of the likelihood of successful improvement in AVA. Serial measurements of transvalvular pressure gradients, by Doppler echocardiography, can be helpful to

Figure 33-3 Effect of Valvuloplasty on Aortic Valve Area

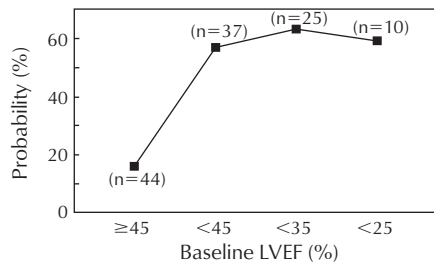


With permission from Waller BF, van Tassel JW, McKay C. Anatomic basis for and morphologic changes produced by catheter balloon valvuloplasty. In: Bashore TM, Davidson CJ, eds. *Percutaneous Balloon Valvuloplasty and Related Techniques*. Baltimore: Williams & Wilkins; 1991:34.



The relation between the aortic valve area and aortic flow (cardiac output). Note the curvilinear relation. The more flat the curves at the smaller aortic valve areas, the greater the gradient at any particular aortic flow. Because of this relation, a change in the aortic valve of 0.3 cm<sup>2</sup> has a much greater impact on the gradient going from 0.5 cm<sup>2</sup> to 0.8 cm<sup>2</sup> (A to B) than the same incremental change going from 0.8 cm<sup>2</sup> to 1.1 cm<sup>2</sup> (B to C).

With permission from Bashore TM, David CJ. *Acute Hemodynamics Effects of Percutaneous Balloon Aortic Valvuloplasty and Related Techniques*. Baltimore: Williams & Wilkins; 1991:105.



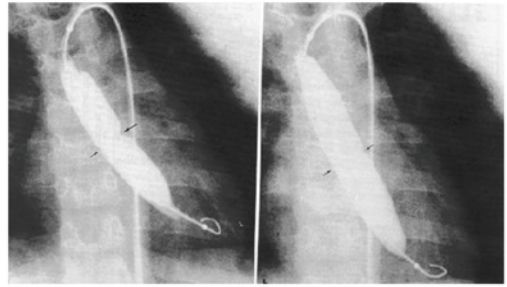
The relation between the baseline ejection fraction (EF) and the probability of recurrent symptoms at the 1-year outcome in elderly patients undergoing percutaneous balloon aortic valvuloplasty. Only those with an EF >45% experienced acceptable results.

With permission from Davidson CJ, Harrison JK, Pieper KS, et al. Determinants of one-year outcome from balloon aortic valvuloplasty. *Am J Cardiol* 1991;68:79.

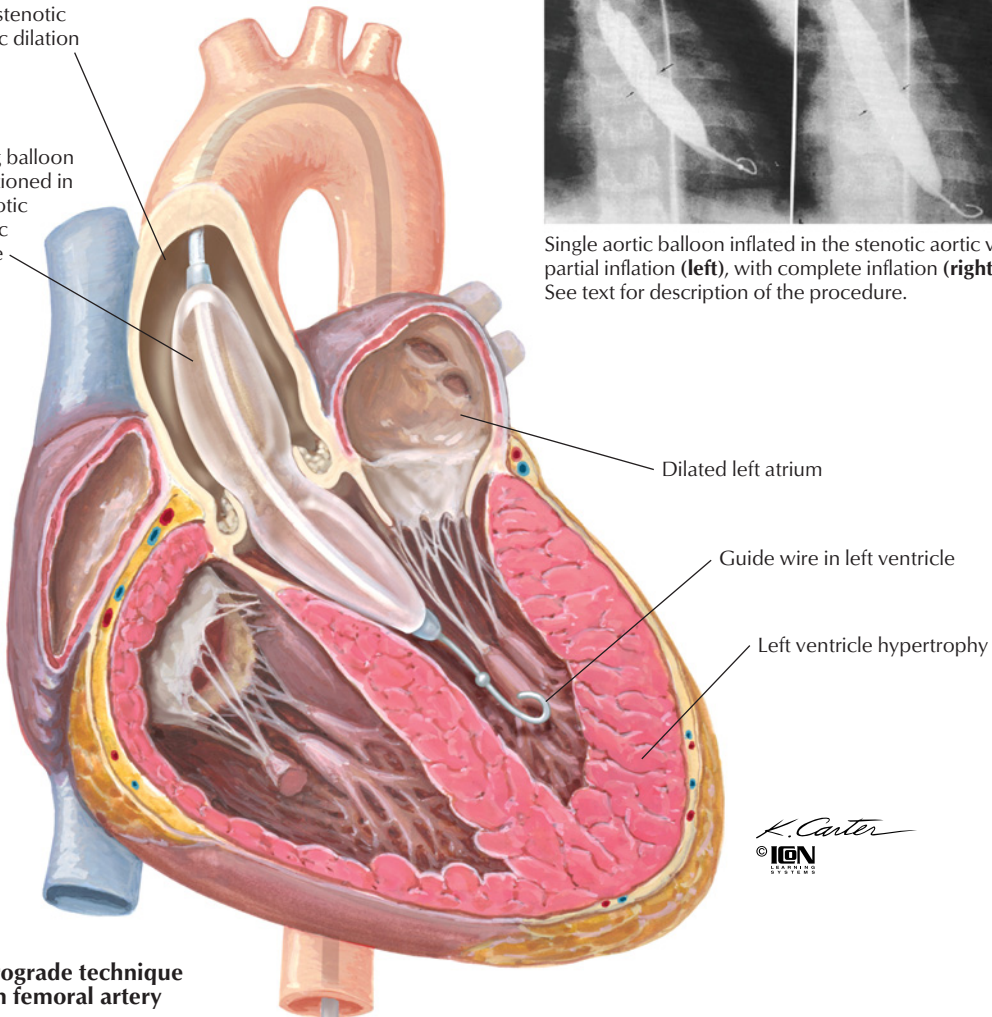
Figure 33-4

Aortic Balloon Valvuloplasty

Poststenotic aortic dilation  
 Long balloon positioned in stenotic aortic valve

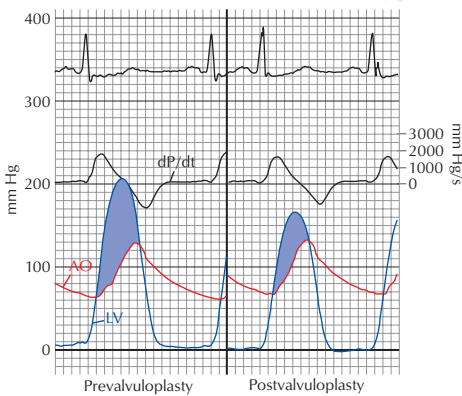


Single aortic balloon inflated in the stenotic aortic valve; partial inflation (left), with complete inflation (right) See text for description of the procedure.



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Retrograde technique from femoral artery



Representative hemodynamic changes

Representative pressure changes before and after percutaneous balloon aortic valvuloplasty. High-fidelity simultaneous LV and aortic pressures are shown with the accompanying dP/dt before and after the valvuloplasty procedure. The aortic gradient before and after is shaded.

With permission from Bashore TM, Davidson CJ. *Acute Hemodynamics Effects of Percutaneous Balloon Aortic Valvuloplasty and Related Techniques*. Baltimore: Williams & Wilkins; 1991:105.

the physician who follows up on the patient. When the maximum velocity exceeds 4 m/sec (estimated gradient of 64 mm Hg), symptoms emerge relatively quickly. A change in the Doppler gradient of more than 0.3 m/sec within 1 year also portends symptoms. Because of the variable means for measuring valvular gradients and the dependence of the valve gradient on the aortic valvular flow and the effective orifice area, the use of a specific AVA to make a decision on operability is tenuous. In symptomatic patients with reduced LV systolic function and poor forward cardiac output, the use of an inotropic agent or nitroprusside to augment aortic flow may help determine whether the low output (and the subsequently low gradient) is a consequence of the valvular stenosis or is attributable to poor ventricular function. Most physicians use an AVA of below 0.8 cm<sup>2</sup> and a mean aortic gradient of at least a 50 mm Hg in symptomatic patients as indications for aortic valve intervention.

Whether to use percutaneous intervention depends on the clinical situation and the type of valvular disease responsible for the aortic valve stenosis. In the rare case of rheumatic aortic valve stenosis without significant aortic insufficiency, commissural fusion is present. Percutaneous balloon valvuloplasty would be expected to be beneficial in this situation, but very few patients have isolated aortic valve stenosis due to rheumatic disease.

In neonates and very young children, the initial success rates for percutaneous intervention are not encouraging, although older children may benefit and should be considered for the procedure. In adults, surgical intervention has consistently proven superior to percutaneous balloon valvuloplasty. The use of percutaneous balloon valvuloplasty in adults should be restricted to situations in which the risk of surgical intervention is very high (e.g., in a pregnant patient or in an elderly patient with cardiogenic shock). In these circumstances, percutaneous balloon valvuloplasty may serve as a bridge to eventual aortic valve replacement. Also, in the rare elderly adult with preserved LV systolic function and severe aortic valve stenosis who is not a candidate for surgical aortic valve replacement because of comorbid conditions, valvuloplasty can provide short-term symptomatic benefit, but long term outcomes are poor.

## Technique

The balloon catheter used for aortic valvuloplasty should have a maximum inflated diameter slightly smaller than the measured size of the aortic annulus. In adults, a 20-mm diameter balloon is usually used, although a 23-mm balloon may be required for larger patients. Smaller sizes are used in children or in very small adults. Longer balloons (i.e., 5.5 cm vs. 3 cm in length) are advantageous to help prevent slippage in the stenotic valve orifice during balloon inflation.

Hemodynamics are measured at baseline and after the completion of the procedure to determine the efficacy of the procedure. The balloon catheter is placed in the middle of the valve plane and inflated, using dilute (25%) radiographic contrast in saline (Fig. 33-4). Inflation pressures do not seem to significantly influence the outcome, and these pressures are no longer measured. Usually one to three separate 15- to 20-second inflations are adequate.

Whether the approach is percutaneous (via the femoral artery, with or without a sheath), cut-down (using the brachial artery), or transseptal (using an antegrade approach to the aortic valve via the right femoral artery), similar results are obtained. The transseptal approach is particularly useful in patients with significant aortoiliac atherosclerosis, which is common in elderly individuals. Following the transseptal puncture, an 0.038-inch wire is navigated through the left atrium and the left ventricle, across the aortic valve, and down the descending aorta for stability. The intra-atrial septum is expanded using an 8-mm balloon catheter before insertion of the aortic valvuloplasty balloon catheter. The remainder of the procedure is similar to the retrograde approach.

## Acute Results and Complications

A review of 18 studies of balloon valvuloplasty in elderly patients showed that the mean aortic gradient can be expected to fall from about 55 to 29 mm Hg acutely, with the AVA increasing from 0.5 to 0.8 cm<sup>2</sup>. Patients in these studies generally had no measurable increase in cardiac output.

In those patients for whom pressure-volume data were derived before and immediately after the procedure, systolic function was largely unchanged, with the ejection fraction rising only slightly, the peak positive dP/dt falling slightly, and



stroke volume and peak and end-systolic wall stress all modestly reduced. A greater impact was noted on diastolic measures of ventricular function, including a significant decrease in peak negative dP/dt and a prolongation of tau (a measure of active diastolic relaxation). Transient mild ischemia during the procedure was considered responsible for some of the acute changes.

Results in children and neonates vary broadly depending on the patient's clinical status and associated cardiac anomalies. Many neonates with critical aortic valve stenosis have severe LV hypoplasia or endocardial fibroelastosis and do poorly with either percutaneous aortic valvuloplasty or surgery. After the neonatal period, the results from valvuloplasty improve. Data from 232 patients with a mean age of about 9 years showed the aortic gradients decreased approximately 60% from about 75 mm Hg to 30 mm Hg after percutaneous balloon valvuloplasty. Thus, the procedure appears to work reasonably well in the adolescent age group, importantly offering an opportunity to delay surgery until the individual has reached their full adult size. It should be noted that, even with an excellent outcome, restenosis will occur over time. This may be a good trade-off because surgical replacement of the aortic valve before adulthood may be followed by a need for subsequent surgery due to relative valvular stenosis (for instance a prosthetic valve that was appropriate in an adolescent may be undersized for the adult heart).

The rate of serious life-threatening complications from aortic valvuloplasty is remarkably low given the elderly population in whom it was initially applied. Almost all protocols require patients to be noncandidates for surgical intervention. In a review of 791 such patients, in-hospital mortality rates of 5.4% with a risk of serious morbidity (cerebrovascular accident, cardiac perforation, myocardial infarction, or serious aortic insufficiency) of up to 1.5%. Vascular complications were overwhelmingly the greatest complicating feature, with a 10.6% incidence.

In the NHLBI registry of 671 patients, complications were significant. At least one complication was reported in 25% of the patients within 24 hours, and 31% had some complication before hospital discharge. The most common

complication was the need for transfusion (23%), followed by the need for vascular surgery (7%) or the occurrence of a cerebrovascular accident (3%), a systemic embolization (2%), or a myocardial infarction (2%). All cause mortality was 3%, with death usually related to multi-organ failure and poor preprocedural LV function. In patients who survived to 30 days, 75% had improved at least one New York Heart Association (NYHA) functional class.

### Long-Term Results

Short-term studies after aortic valvuloplasty have revealed that an increase in the aortic gradient can occur as early as 2 days after the procedure, undoubtedly related to aortic recoil. There may also be progressive early improvement in cardiac output over this initial period that, while beneficial, adds to the increased gradient observed. By 6 months, most patients have evidence of restenosis. In a study of 41 patients undergoing recatheterization at 6 months, essentially all of the patients demonstrated hemodynamic restenosis. Of interest, symptoms at follow-up appear more related to diastolic dysfunction than to the measured AVA or gradient.

In one study, at 1-year follow-up, the probability of recurrent symptoms was predicted by a baseline ejection fraction below 45. This implies that patients with poor LV systolic function are not good candidates for percutaneous balloon aortic valvuloplasty. Because most patients with preserved LV systolic function would clearly be candidates for aortic valve replacement surgery, only a small population of adult patients would be expected to benefit from the resultant short-term improvement in symptoms. This situation is most likely to occur in those aortic valve stenosis patients at an extreme age (over 90 years), in whom the risk of surgery is usually prohibitive.

## MITRAL VALVE STENOSIS

### Pathophysiology

Obstruction to LV inflow through the mitral valve is usually attributed to rheumatic heart disease. Congenital mitral valve stenosis (MS) may also occur, generally from chordal fusion, often to each other, or abnormal papillary muscle positioning. The papillary muscles may be so

close that a single papillary muscle is evident (parachute mitral valve). Rarely, a mitral web on the atrial side of the mitral leaflet can obstruct flow. In the elderly, mitral valve annular calcification may result in leaflet stiffening and MS, in which calcium invades from the annulus toward the center of the valve; mitral regurgitation (MR) is frequently associated. Other causes of MS are rare: carcinoid (usually associated with a patent foramen ovale or an atrial septal defect), systemic lupus erythematosus, rheumatoid arthritis, Fabry's disease, and amyloidosis. Rheumatic involvement predominates as a cause for MS, however, and other valves are often involved as well.

The interval between an episode of acute rheumatic fever and symptomatic MS averages about 16 years. Most patients do not recall the acute event when they ultimately present with MS. Fusion of the commissures between the anterior and posterior leaflets is the most characteristic feature of rheumatic MS. Fusion, thickening, and retraction of the chordae; thickening of the valvular leaflets; and calcium deposition contribute to the obstructive process. The severity of these features has led to an echocardiographic qualitative scoring system in which numbers are assigned to each characteristic. The mobility of the anterior mitral valve leaflet, the presence of valvular thickening or submitral scarring, and evidence of calcification are weighted into a score to help define the suitability of the valve for percutaneous valvuloplasty (discussed under Indications). Figure 33-5 represents the spectrum of involvement from chest wall two-dimensional echocardiography.

The location of the commissural fusion may help predict success of balloon dilation. Because the procedure works by tearing the commissural fibrosis that causes leaflet fusion, the presence of minimal commissural fusion suggests that the procedure will be ineffective. If there is eccentric commissural fusion on only one side of the leaflet, the inflated balloon(s) might be forced to the nonfused side of the leaflet, increasing the risk of valvular or ventricular trauma. If the fusion is only on the septal side of the mitral valve, for instance, the risk that the inflated balloons will tear into the mitral annulus increases.

The area of the mitral valve measured by planimetry usually correlates well with the

Doppler-derived valve area. When the planimetric area seems much larger than the Doppler-derived area, this dichotomy may signal the presence of a significant submitral gradient. Such a valve may not respond to balloon valvuloplasty.

## Indications

Mitral valve stenosis results in obstruction to LV inflow and an elevated left atrial (LA) pressure. Any activity that increases flow (e.g., exercise) or shortens diastolic time (e.g., the onset of a rapid tachycardia, such as atrial flutter or fibrillation) increases the mitral gradient. When the pressure gradient across the mitral valve is increased, symptoms of dyspnea and pulmonary congestion emerge. The decision to intervene in MS is based primarily on exertional symptoms.

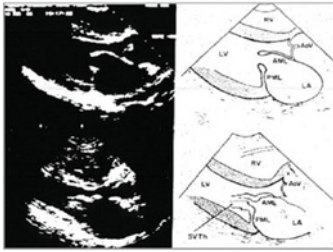
Pulmonary hypertension that is greater than would be expected from the magnitude of the left atrial pressure alone may be present. Pulmonary hypertension is also an indication for correcting the valvular stenosis; significant improvement can be expected after the procedure. Pulmonary vascular resistance only roughly correlates with the MVA. Pulmonary vascular resistance can be disproportionately elevated compared with the pulmonary capillary wedge pressure. Although the trigger for the excessive elevation in the pressure of the pulmonary artery is unknown, endothelin and adrenomedullin, both potent pulmonary vasoconstrictors, may be involved. Because pulmonary hypertension in this situation may regress following balloon valvuloplasty, pulmonary hypertension or right-sided heart failure even without congestive symptoms is an indication for intervention in MS.

Whether to proceed with valve replacement or valvuloplasty depends on the morphology of the stenosed mitral valve. Several echocardiographic scoring systems have been suggested, the most popular being the Massachusetts General Hospital system, in which each of four characteristics is graded 0 to 4, with 0 being normal (Table 33-1). The higher the score, the less likely it is that a satisfactory result will be by percutaneous balloon dilation. The scoring system has successfully predicted acute results in many studies; a score greater than 8 is more likely to be associated with a suboptimal result. When treated as a continuous

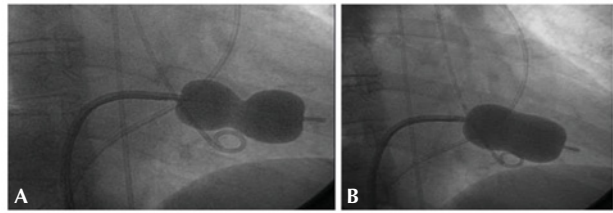
**Figure 33-5**

**Mitral Balloon Valvuloplasty**

**Echocardiographic scoring of mitral valve stenosis severity**

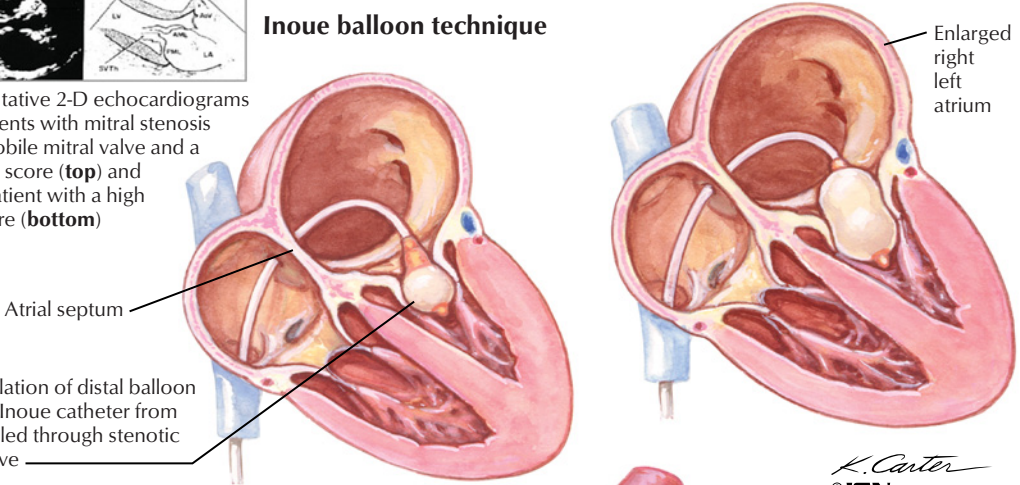


Representative 2-D echocardiograms from patients with mitral stenosis with a mobile mitral valve and a low echo score (**top**) and from a patient with a high echo score (**bottom**)

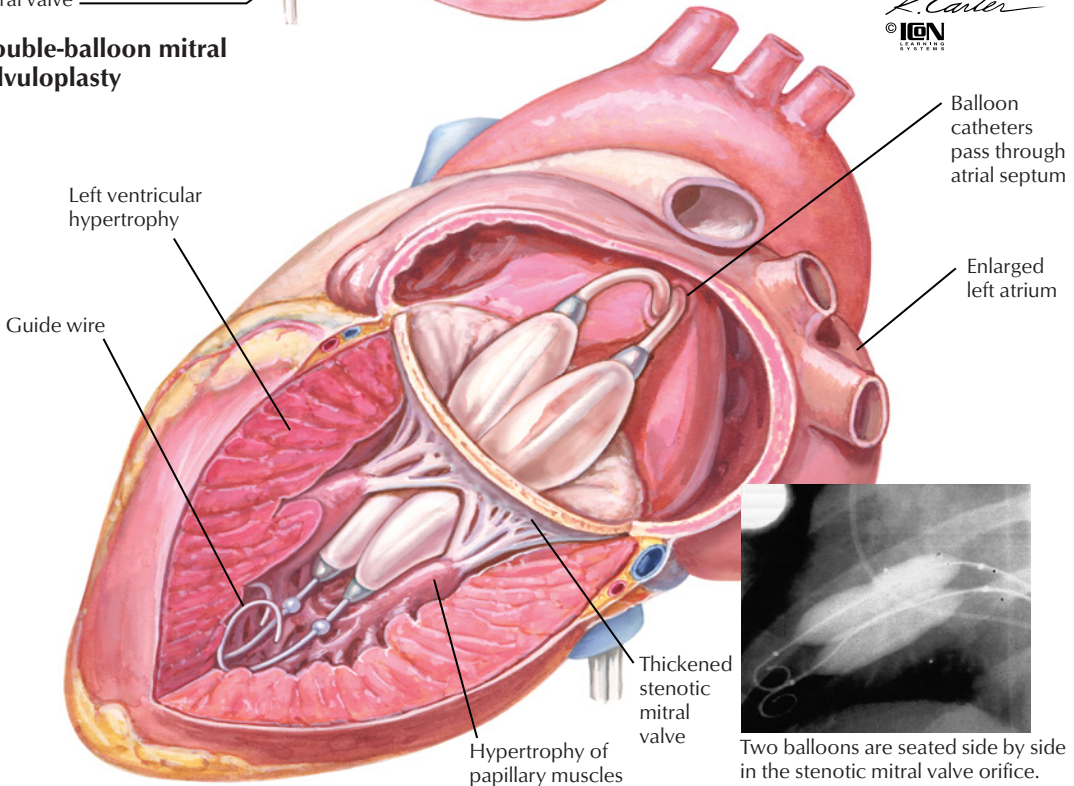


**Inoue balloon mitral valvuloplasty.** The Inoue balloon is seen partially inflated in the stenotic mitral valve orifice on the right (**A**) and fully inflated on the left (**B**). See text for description of the procedure.

**Inoue balloon technique**



**Double-balloon mitral valvuloplasty**



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**Table 33-1**  
**Anatomic Classification of the Stenotic Mitral Valve: The Massachusetts General Hospital Scoring System**

Measurement	Valve Score
A. Leaflet mobility	<ol style="list-style-type: none"> <li>1. Highly mobile valve with only leaflet tip restriction</li> <li>2. Midportion and base of leaflets with reduced mobility</li> <li>3. Valve leaflets move forward in diastole mainly at the base</li> <li>4. No or minimal forward movement of the leaflets in diastole</li> </ol>
B. Valvular thickening	<ol style="list-style-type: none"> <li>1. Leaflets minimally thickened (4–5 mm)</li> <li>2. Midleaflet thickening, pronounced thickening of the margins</li> <li>3. Thickening extends through the entire leaflets (5–6 mm)</li> <li>4. Pronounced thickening of all leaflet tissue (&gt;8 mm)</li> </ol>
C. Subvalvular thickening	<ol style="list-style-type: none"> <li>1. Minimal thickening of chordal structures just below the valve</li> <li>2. Thickening of the chordae extending up to one third of the chordal length</li> <li>3. Thickening extending to the distal third of the chordae</li> <li>4. Extensive thickening and shortening of all chordae extending down to the papillary muscles</li> </ol>
D. Valvular calcification	<ol style="list-style-type: none"> <li>1. A single area of increased echo brightness</li> <li>2. Scattered areas of brightness confined to the leaflet margins</li> <li>3. Brightness extending to the midportion of the leaflets</li> <li>4. Extensive brightness through most of the leaflet tissue</li> </ol>
Assessment	A “0” score implies normal valve morphology. A total valve score of ≤8 implies a mobile valve amenable to percutaneous valvuloplasty. Progressively higher total valve scores result in less favorable outcomes, both acutely and long term.

With permission from Wilkins GT, Weyman AE, Abascal VM, Block PC, Palacios IF. Percutaneous balloon dilatation of the mitral valve: An analysis of echocardiographic variables related to outcome and the mechanism of dilatation. *Br Heart J* 1988;60:299–308.

variable, however, the relationship between the morphology score and either the increase in MVA or the final MVA after the procedure is relatively poor. The scoring system weighs each factor equally, even though certain factors may weigh more heavily toward a negative result than others. For instance, commissural calcium may be a stronger predictor of outcome than the total score.

Before the procedure, patients should undergo transesophageal echocardiography to ensure that no atrial thrombus is present and to provide an additional assessment of the valvular morphology. If an atrial thrombus is present, patients are placed on warfarin for 4 to 6 weeks and the transesophageal echocardiography is repeated. The procedure can be done when an atrial thrombus is deep inside the appendage,

but resolution of any atrial clot before proceeding is advisable.

Patient age or a history of surgical commissurotomy does not significantly influence the acute results of the procedure, provided the valvular morphology is favorable. In general, a symptomatic patient with a reasonably low morphology score and less than 2+ MR is a candidate for percutaneous mitral valvuloplasty. Essentially all patients with symptoms related to MS have a calculated MVA of less than 1.5 cm<sup>2</sup>.

**Technique**

Early experience and suboptimal results with single-balloon techniques initially prompted the development of double-balloon techniques. Since then, a unique single-balloon technique using the Inoue balloon has become popular.

Most laboratories use an antegrade method that requires transseptal catheterization. Right-sided heart catheterization and ventriculography initially determine the degree of MR, cardiac output, pulmonary pressure, the valve gradient, and the MVA. Some interventionalists use a right atrial angiogram with LA levophase filling to guide transseptal needle placement.

Transseptal catheterization uses a hollow Brockenbrough needle within an 8F Mullins sheath. Continuous pressure monitoring alerts the operator if the needle punctures the aorta or enters the pericardium. Once the sheath has been advanced into the left atrium, the needle is removed, the mitral gradient remeasured, and the MVA obtained.

Double-balloon techniques are complex. Some operators favor using double balloons that are positioned side by side using two guidewires. Other systems are available that use two balloons on a single catheter (the bifoil system) or two balloons on a single guidewire (the Multi-Track System). In any approach, the dilating balloons are then positioned side by side across the mitral valve and simultaneously inflated one to four times with dilute contrast (Fig. 33-5). When the procedure is completed, the mitral gradient is remeasured and the left ventriculogram repeated to assess any residual MR.

The Inoue balloon method simplifies the procedure. The 12F balloon catheter is designed so the distal end of the balloon inflates before the proximal end, allowing balloon positioning across the mitral valve, inflation of the distal end, and pulling of the remaining balloon into the mitral orifice before inflation of the entire balloon. With double balloons, the maximum diameter is predetermined and dependent on the inflated maximum balloon diameter(s). With the Inoue system, the diameter depends on the amount of contrast used to inflate the balloon. This feature allows for graded increases in the diameter of the balloon during the procedure without replacing the entire balloon catheter. The balloon size can be determined from echocardiographic measurements of the mitral annulus or by the patient's height. The most commonly used sizes are maximum diameters of 26 mm and 28 mm.

Once in the left ventricle, the balloon is sequentially inflated in the mitral valve orifice in incre-

ments of 1 to 2 mm. The LA pressure and the mitral gradient are reevaluated following each balloon inflation. Echocardiography of the chest wall between each inflation allows observation of any change in the mitral valve and any Doppler evidence of MR. If MR is present or if the valvular gradient has been satisfactorily reduced, the procedure is completed. Repeat cardiac output measures, a shunt run to evaluate evidence of any atrial septal defect created by the transseptal puncture, and repeat right-sided heart pressures are then performed before the postprocedural ventriculogram. A final valve area greater than 1.5 cm<sup>2</sup> with no more than 2+ MR is the goal.

### Acute Results and Complications

Immediate improvement in the hemodynamic and clinical outcomes was found in all 19 studies that addressed the immediate results of mitral valvuloplasty. A 50 to 70% decrease in the transmitral gradient with an accompanying 50 to 100% increase in the MVA is a reasonable expectation based on these studies. A representative example would be a preprocedural MVA of 0.9 cm<sup>2</sup> improving to a postprocedural MVA of 1.9 cm<sup>2</sup>. Similarly, a representative preprocedural mitral gradient would be about 14 mm Hg before and 6 mm Hg following valvuloplasty. Cardiac output tends to remain unchanged. The postprocedural valve areas are similar with the double-balloon method and the Inoue system. About 8 to 10% of valve areas will not improve to a final valve area of greater than 1.0 cm<sup>2</sup>.

Pulmonary pressures fall immediately, consistent with the change in LA pressure. In patients with severe pulmonary hypertension, the pulmonary pressures drop further by 24 hours and continue to decline during the ensuing months.

The issues involved in the relationship between the valve area and valve flow discussed in the assessment of the results of aortic valvuloplasty also pertain mitral valvuloplasty. A successful procedure is generally defined as a 50% improvement in the MVA or a final MVA of more than 1.5 cm<sup>2</sup> plus no more than 2+ MR. An acute success rate of about 90% can be expected, depending on the valvular morphology. The major factors identified as predictive of success are a low valvular score by whatever method and the absence of significant baseline MR.

Complications from percutaneous mitral valvuloplasty have declined as the learning curve of the procedure has improved, and the procedure has largely been restricted to the relatively few centers that perform the procedure frequently. Table 33-2 summarizes figures for acute complications from several reviews. With the routine use of transesophageal echocardiography before the procedure, the risk of embolic events has virtually disappeared. Major complications are related to the transeptal technique and the development of significant MR from injury to the mitral valve apparatus. The use of serial echocardiography following each balloon dilation has increased awareness of any developing MR, allowing the procedure to be aborted before serious MR develops. Careful attention to the change in the LA v wave during the procedure is also important, with an increase predictive of acutely worsening MR.

**Long-Term Results**

*Survival and Event-Free Survival Data*

Ten-year survival rates have been reported at 85 to 97%, with event-free survival rates of 61 to 72%. Event-free survival appears to be dependent on optimal valve morphology, the presence of sinus rhythm, lower MVA pressures, and no more than 2+ MR following the procedure. A review of the Massachusetts General Hospital experience showed that although incidence of adverse events (death, mitral valve surgery, and redo-valvuloplasty) were low within the first 5 years of follow-up, a progressive increase in adverse events occurred beyond this period, probably related more to the disease process more than to complications of the procedure. Survival (82% vs. 57%) and event-free survival (38% vs. 22%) rates at 12-year follow-up were better in patients with an echocardiography score of 8 or below than in those with scores above 8. Cox regression analysis identified independent predictors of combined events at long-term follow-up: postvalvuloplasty MR of 3+ or more, an echocardiography score above 8, older age, prior surgical commissurotomy, NYHA functional class 4, prevalvuloplasty MR of 2+ or more, and higher postvalvuloplasty pulmonary artery pressure. Atrial fibrillation has a negative effect on event-free survival, and some reports have

**Table 33-2**  
**Contemporary Complications**  
**Associated With Percutaneous**  
**Mitral Valvuloplasty**

<i>Complication</i>	<i>Estimates (%)</i>
Emergency cardiac surgery	1–4
Cardiac perforation/tamponade	0.5–4
Significant mitral regurgitation	2–3
Cerebrovascular accident/ embolic events	0.5–1.5
Death	0–1

also noted the negative effect of valvular calcium and baseline MR. As expected, patients with sub-optimal initial results do less well clinically.

*Symptomatic Improvement and Restenosis*

Essentially all studies emphasize the impressive improvement in patients' symptoms after percutaneous balloon mitral valvuloplasty. Symptoms are more likely to occur in patients with suboptimal results and in those with poorer valve morphology. Postprocedural restenosis is difficult to define because of issues related to the definition of an initial hemodynamic success. Initial studies defined restenosis as at least 50% loss of the initial MVA gain, whereas other studies have advocated including an MVA of less than 1.5 cm<sup>2</sup> in the definition.

Serial hemodynamic studies suggest that clinical restenosis may not correlate well with anatomic restenosis. One report of serial echocardiographic restenosis data in 310 patients with high baseline echocardiography scores assessed restenosis, defined as an MVA of less than 1.5 cm<sup>2</sup> and/or at least 50% loss of the initial MVA increase. Acute procedural success (a final valve area >1.5 cm<sup>2</sup>) occurred in 66% of patients. The cumulative restenosis rate was about 40% at 6 years after successful valvuloplasty. The only independent predictor of restenosis was the echocardiographic score (the probability of restenosis at 5 years was 20% for scores <8 vs. 61% for scores ≥8). The decline in MVA and the occurrence of restenosis were gradual and progressive during follow-up. Echocardiographic restenosis was related to adverse events or to

NYHA functional class 3 or 4 symptoms, but it was not an independent predictor of clinical outcome by multivariate analysis.

Clinical restenosis data are more impressive. Mitral valve anatomy always appears to predict the symptomatic outcome. Clinically, the restenosis rate has been reported at 20 to 39% at 7 years after valvuloplasty. A 10-year clinical restenosis rate of 23% was found for those with an echocardiography score of 8 or lower, 55% for those with an echocardiography score of 9 to 11, and 50% for those with a score of 12 or higher.

### *Comparative Data With Surgical Commissurotomy*

Studies comparing surgery and balloon valvuloplasty have shown similar initial results. In 60 patients with favorable anatomy randomized to valvuloplasty (using the double-balloon technique) or open surgical commissurotomy, excellent early results were reported with both techniques. However, at 3 years, the MVAs of the balloon valvuloplasty patients were actually better than those of the surgical group (2.4 cm<sup>2</sup> vs. 1.8 cm<sup>2</sup>) and 72% of the valvuloplasty patients were in NYHA functional class 1 compared with 57% of the surgical group.

In another study, 90 patients were randomized to valvuloplasty, open commissurotomy or closed commissurotomy and were followed for 7 years. Little difference existed between the valvuloplasty patients and the open commissurotomy patients at the conclusion of the study. The valvuloplasty and open surgical procedure groups had less clinical restenosis than the closed commissurotomy group (0% for the valvuloplasty and open commissurotomy groups, 27% for the closed surgical group). At 7 years, 87% of the valvuloplasty patients and 90% of the open commissurotomy patients were in NYHA functional class 1 compared with 33% of the closed surgical commissurotomy patients.

It appears that balloon valvuloplasty is equivalent or superior to surgical commissurotomy for symptomatic MS, at least through the first 7 years after the procedure, as long as the preprocedural valve score falls within an acceptable range. Hence, the percutaneous approach is advocated in those with appropriate valve morphology.

## TRICUSPID VALVE STENOSIS

### **Pathophysiology**

Tricuspid valve anatomy is more variable than mitral anatomy. The three leaflets of the tricuspid valve are of unequal size; the septal leaflet is the smallest, the anterior leaflet the largest. Although some chordae attach to distinct papillary muscles in the right ventricle, they also attach directly to the right ventricular endocardium. Therefore, tricuspid regurgitation is a frequent occurrence when the right ventricle dilates from any cause. The orifice of the tricuspid valve is considerably larger than the mitral orifice, the normal tricuspid valve area being about 10 cm<sup>2</sup>. Considerable valve stenosis must be present to obstruct the RV inflow. Although a mean gradient of 2 mm Hg establishes the diagnosis, most consider a mean gradient of at least 5 mm Hg or a calculated valve area of less than 2.0 cm<sup>2</sup> to indicate significant tricuspid valve stenosis (TS).

Tricuspid valve stenosis is decidedly uncommon and never an isolated lesion. Rheumatic disease accounts for 90% of cases of TS. Of patients with rheumatic mitral valve disease, about 3 to 5% have associated TS. Commissural fusion is present, but the fibrosis and/or the fusion of the chordae is seen less often than is observed in rheumatic MS. Leaflet calcium is also uncommon.

In the United States, the second most common cause of TS is carcinoid syndrome, in which tricuspid regurgitation is also usually present. Carcinoid plaque thickens the leaflets and the chordae, and commissural fusion is unusual. Congenital forms of TS exist and are generally due to abnormalities in the leaflets (absent or decreased number), the chordae (absent, reduced number, or shortened) and the papillary muscles (reduced number). Percutaneous balloon techniques have been attempted in congenital TS, but the role of these techniques is limited in the treatment of this condition.

Open surgical commissurotomy on the tricuspid valve is also rarely performed because of the high risk of tricuspid regurgitation. It is inadvisable to open the commissure between the anterior and posterior leaflets, although surgical commissurotomy may succeed if fusion is relieved between the anterior and septal or the

posterior and septal leaflets. On the basis of surgical experience, the use of balloon valvuloplasty seems anatomically limited.

## Indications

Patients with TS usually present with low cardiac output, fatigue, anasarca, and abdominal swelling from hepatomegaly and ascites. Giant a waves may be visible in the neck and even felt by the patient. Symptomatic TS is an acceptable reason to consider intervention. The limiting factor is usually associated tricuspid regurgitation. The procedure could be considered in the unlikely circumstance that a patient was not a surgical candidate and had limited tricuspid regurgitation or would clinically benefit from conversion from TS to tricuspid regurgitation.

## Procedure and Results

There are few data on the use of percutaneous balloon tricuspid valvuloplasty. The technical aspects are similar to percutaneous mitral valvuloplasty except that no transseptal procedure is required. In the NHLBI Balloon Valvuloplasty Registry, only three patients underwent the procedure on a native valve.

Most tricuspid valvuloplasty procedures have been performed in patients who had both mitral and tricuspid valvuloplasty at the same setting. Results of these procedures have been mixed in the treatment of TS from carcinoid syndrome. No long-term reports exist about the efficacy of tricuspid valvuloplasty in any setting.

## BIOPROSTHETIC VALVE STENOSIS

### Pathophysiology

Porcine or bovine pericardial prosthetic valves may be implanted in any valvular position. All of these valves have a limited lifespan because of eventual mineralization and collagen degeneration. Cuspal tears, fibrin deposition, disruption of the fibrocollagenous structure, perforation, fibrosis, and calcium infiltration appear after a few years; by 10 years, tissue valve failure occurs in about 30% of patients. By 15 years, more than 50% of the valves have failed. The degenerative structural changes occur earlier in valves in the mitral compared with the aortic position, because of greater hemodynamic stress on the mitral valve. Patients on dialysis appear to be particular-

ly susceptible to early valve failure. Other identified factors associated with valve failure include younger age, pregnancy, and hypercalcemia.

Commissural fusion is uncommon in these valves, the major problem being leaflet immobility. At times, these valves become relatively stenotic from undersizing (patient-prosthetic mismatch). From an anatomic standpoint, the use of percutaneous balloon valvuloplasty procedures appears problematic given the lack of commissural fusion.

## Prosthetic Valvuloplasty

Limited data exist about the use of balloon procedures in prosthetic valve stenosis. Success in two patients with porcine TS has been described, although limited follow-up data were available and "restenosis" quickly occurred in one patient. The NHLBI Balloon Valvuloplasty Registry reported four successful procedures with no follow-up. In every instance of our investigations of explanted porcine valves, considerable trauma occurred to the explanted valve and balloon techniques did not appear to be a viable option. No prospective studies have addressed the safety and efficacy of this procedure, and on the basis of the evidence available, it is not recommended.

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