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## Balloon Aortic and Pulmonic Valvuloplasty

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### INTRODUCTION

Valve replacement for aortic valve stenosis has been the gold standard of therapy for decades. The prognosis of symptomatic severe aortic stenosis is well known, with very high annual mortality and a clearly limited life-span. Surgical aortic valve replacement with a mechanical prosthesis, bioprosthetic, or homograft valve prolongs life in this patient cohort.

The development of balloon catheter aortic valvuloplasty in the mid-1980s initially promised to provide an alternative to valve replacement in patients suitable for this procedure. Early experience with the procedure showed balloon catheter therapy to have limited durability, with restenosis a near certain finding in most adult patients undergoing the procedure (1–4). Accordingly, balloon aortic valvuloplasty (BAV) has found a place in the therapeutic armamentarium for aortic stenosis only among those patients for whom surgical aortic valve replacement is either contraindicated or carries extremely high surgical risk (5). These older patients with symptomatic aortic stenosis have a 1-yr survival of 55–75% and a 1-yr event-free survival of only 40–50% (2–4).

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**Table 1**  
**Balloon Valvuloplasty in the Young Adult Age  $\leq 21$  Years**

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**Class I**

- Symptoms with peak gradient  $>50$  mm Hg
- Gradient  $>60$  mm Hg
- New ECG changes at rest or with exercise  $>50$  mm Hg

**Class IIa**

- Gradient  $>50$  mm Hg in patient who desires competitive sports or pregnancy

**Class III**

- Gradient  $<50$  mm Hg with no symptoms or ECG changes
- 

## PATIENT SELECTION FOR BALLOON AORTIC VALVULOPLASTY

Patient selection for BAV is challenging. The American Heart Association–American College of Cardiology task force guideline recommendations for therapy with BAV defines a narrow patient population (6). Balloon valvuloplasty is the treatment of choice for aortic stenosis in children and young adults age 21 yr or less with aortic stenosis. Table 1 provides a list of specific indications. In the younger population, valve stenosis severity is defined by gradient, because many of these patients will be growing and have a variable valve area. BAV in this group of patients is durable, and an expectation for good long-term results is extremely different than that seen in older adult patients with aortic valve stenosis. When patients present under 30 or 40 yr of age, it is likely that they have congenital aortic stenosis. When these patients present beyond age 21 or 22 yr, the results of valvuloplasty are less satisfactory. The valve leaflets at this point are usually fibrotic but not calcified and do not respond as well to balloon dilatation as in patients age 21 yr and younger. Patients who present at age 55–70 are likely to have bicuspid aortic stenosis. When the bicuspid valve is heavily calcified BAV might have an outcome similar to patients with calcified degenerative aortic stenosis.

A second group in whom long-term results of BAV can be expected to be durable are those with rheumatic aortic valve stenosis. When patients present with symptoms and aortic stenosis between ages 40 and 60 yr, the disease might be rheumatic in origin. This is an uncommon group of patients, especially in the United States. Because commissural fusion is the mechanism of stenosis in these patients, BAV yields anatomic results that are similar to balloon mitral commissurotomy. Long-term results of BAV are probably better than in senile calcific aortic stenosis. Few data are available on this particular subset, but adult patients in the United States who present under age 60 without a bicuspid valve might often be inferred to have rheumatic stenosis.

The typical patients treated with BAV in the United States are older adults with calcific aortic stenosis. Because results with aortic valve replacement are well established, valvuloplasty is applied generally only when aortic valve replacement is either relatively contraindicated or strategically better to defer. Table 2 presents the Joint Task Force recommendations on the use of balloon valvuloplasty in adult patients (6). There are no Class I indications in this group.

The guidelines recommend balloon valvuloplasty as a bridge to aortic valve surgery in hemodynamically unstable high-risk patients, so that they can be stabilized. Patients who present in cardiogenic shock or who are “stuck” on pressor agents in an intensive care unit are typical of patients in this group. Palliation for patients with serious comorbid

Table 2  
Balloon Valvuloplasty in Adults with Aortic Stenosis

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Class I

There are no Class I indications

Class IIa

Bridge to surgery in unstable, high-risk patients for valve replacement

Class IIb

Palliation in patients with serious comorbid conditions

Prior to urgent noncardiac surgery

Class III

Alternative to aortic valve replacement surgery

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conditions is, in practice, probably the most common use of BAV in older adults. Patients who are felt to be at high risk for general anesthesia, those who are elderly and have already had prior sternotomy and bypass, and patients who are simply very elderly represent the typical patients in this setting. Patients with prior bypass surgery, prior mitral valve replacement or repair, a heavily calcified or “porcelain” aorta, severe chronic lung disease, or multiple comorbidities are typical. The ambulatory but very elderly are the best candidates. BAV is also used prior to noncardiac surgery in patients found to have tight aortic valve stenosis on preoperative screening. Those who require extensive cancer surgery are typical of this group. BAV is specifically contraindicated as an alternative to aortic valve replacement. Patients who simply say they wish not to have valve replacement, who are otherwise a good candidate for valve replacement, are prototypic of this situation.

A group in whom BAV should be used with extreme caution comprise those who appear to be in the terminal stages of aortic valve stenosis. Patients who have deteriorated over a long period of time, are very elderly, and are intensive care unit bound with the early stages of multiple-organ failure or sepsis cannot realistically be expected to respond to BAV in many cases. Patient selection in this last group is exceedingly important, and it is critical to try to offer this therapy to patients with multiple comorbid conditions early in their course, before they are no longer salvageable. Procedure timing is similarly crucial in the hemodynamically unstable patient where the early benefit of BAV must be weighed against the risk of further multiorgan failure that could result from delaying surgery.

One situation not clearly addressed by the guidelines are those patients who present with low gradient and low cardiac output, in whom it is uncertain whether aortic valve replacement will result in improved left ventricular function. Among those patients who have a poor response to valve replacement, mortality is extremely high. BAV offers a potential opportunity to see if relief of the aortic stenosis will result in improved left ventricular function, although no studies have assessed or validated this approach. These patients are similar to those described in Table 2 as having BAV as a bridge to surgery. In those who improve, valve replacement surgery might be contemplated. BAV is thus used as a therapeutic trial or as a diagnostic test. Among those in whom ventricular function has deteriorated beyond the point where recovery is possible or who have left ventricular dysfunction because of an etiology other than aortic stenosis, lack of improvement is a signal that valve replacement surgery will not offer functional improvement and should not be pursued further.

## ASSESSMENT OF AORTIC STENOSIS SEVERITY

Of critical importance is proper assessment of aortic stenosis severity in potential candidates for BAV. Many times, these patients present with multiple comorbid illnesses, including chronic lung disease. Many also have severe left ventricular failure and depressed left ventricular systolic function and associated hemodynamic lesions, including mitral regurgitation, pulmonary hypertension, and depressed cardiac output. Accordingly, the assessment of the severity of aortic stenosis is a key element in the evaluation of patients for this procedure.

A variety of technical and practical limitations make measurement of valve area difficult. The technical challenges include the inaccuracies of the commonly used disposable pressure transducers, measurement artifacts because of temporal delay of pressure transmission in fluid-filled catheter systems, nonsimultaneous pressure recordings, pressure damping, and the effect of a catheter across the stenotic aortic valve.

The ideal methods for measurement of transvalvular gradient utilized simultaneous acquisition of left ventricular and central aortic pressure with high-fidelity transducers (7,8). This approach is not practical, and a variety of compromises are made in the assessment of aortic valve stenosis.

In practice, the most common method for assessment of aortic stenosis severity is the simultaneous use of a left ventricular pigtail passed retrograde across the valve, compared to a femoral arterial sheath. Use of a pigtail one French size smaller than the sheath and use of a longer-length sheath helps minimize pressure damping in the sheath and pressure amplification in the iliofemoral system. Nonetheless, in cases where the gradient and cardiac output are low, this may yield results significantly different from those obtained when two central aortic catheters are used. Bilateral femoral arterial access may be used to place a left ventricular and central aortic catheter simultaneously. Alternatively, transseptal access to the left ventricle via the venous system with a central aortic catheter placed via the femoral artery will yield excellent results without the additional risks of a second arterial puncture (9). A recent report described a silent cerebral embolism after retrograde catheterization of the aortic valve among patients with valvular stenosis (10). In this randomized study, typical methods to cross the valve retrograde were used in 152 patients. Twenty-two percent who underwent retrograde catheterization had focal diffusion imaging abnormalities on magnetic resonance scans. The transseptal approach eliminates this issue.

The use of a 0.014-in. pressure wire has been described to simplify high-quality central pressure measurements (7). After the aortic valve is crossed retrograde with a conventional 4F or 5F diagnostic catheter, a pressure wire can be passed into the left ventricular apex and the diagnostic catheter withdrawn into the aortic root. This yields remarkably high-quality pressure tracings, visually comparable to those achieved with a high-fidelity micromanometer catheter system.

Patients with low gradient and low cardiac output are the most difficult to evaluate. In addition to scrupulous attention to the quality of pressure recordings and using central aortic pressure compared to left ventricular pressure, a dobutamine infusion to increase the cardiac output by 20–30% will often help in establishing a more accurate measure of the severity of aortic valve stenosis. In some cases, the valve area will appear to increase with increased cardiac output (11–13). This illustrates the so-called flow dependence of the Gorlin equation. In cases of a truly tight aortic valve strength, the valve area will remain constant or sometimes even appear to diminish with an increase in cardiac output.

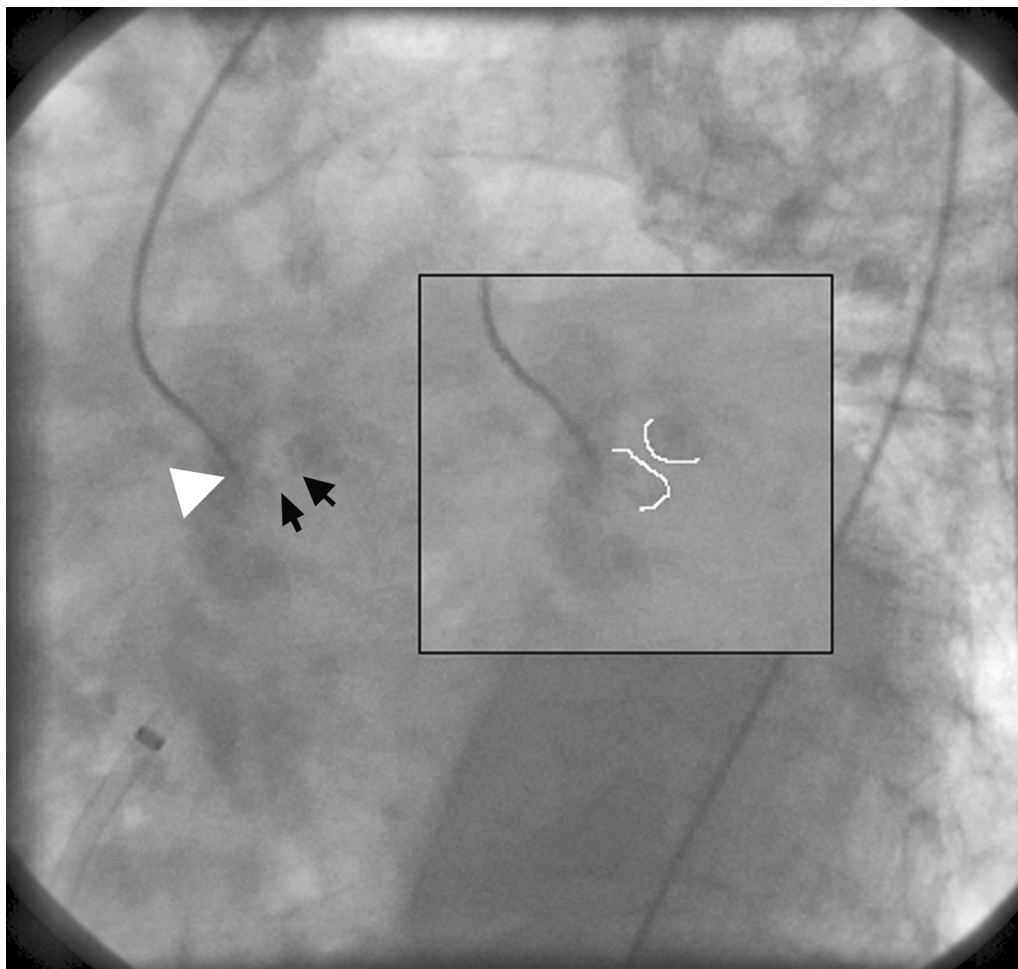
## RETROGRADE TECHNIQUE FOR BALLOON AORTIC VALVULOPLASTY

The retrograde technique basically involves passing a balloon catheter via the femoral arteries retrograde through the aortic arch and across the valve (14,15). The major limitations of the technique are the requirement for a large caliber arterial sheath and the difficulty in maintaining balloon position in the aortic valve during balloon inflations.

After arterial access is gained, using a relatively small caliber (6–8 French) sheath, femoral arteriography is performed to verify the position of the sheath in the common femoral artery. Unless a superficial femoral artery is of exceptionally large caliber, placement of the sheath below the femoral bifurcation precludes use of that puncture for passage of a larger valvuloplasty sheath. Preclosure using a suture closure system can be performed at this point (16,17). Using the existing small caliber sheath, a 6 French or 10 French Perclose device can be preplaced in the arteriotomy and the sutures left dangling. A wire is replaced in the Perclose device, and the device is exchanged for a 12.5 up to 14 French arterial sheath.

A diagnostic catheter is used to pass a wire retrograde across the aortic valve. The technique for crossing the valve retrograde merits some discussion. The use of a specially shaped curved diagnostic catheter (Aortic Stenosis Catheter; Cook Inc., Bloomington, IN) has the advantage of being able to orient the tip of the catheter and thus the direction of wire passage toward the center of the aortic root. The catheter has a gentle curve similar to that of an Amplatz shape and, in addition, has a very soft distal end and side holes (14). The soft distal end allows the catheter to track more easily over a wire, once the wire has been passed into the left ventricle. The side holes permit ventriculography if needed. The catheter is positioned above the aortic valve and gently rotated until the tip of the catheter is as close to the center of the root as possible. The pattern of calcification in the aortic leaflets helps with catheter positioning. Figure 1 shows the diagnostic catheter with the tip pointing just to the right of the orifice of the aortic valve in a left anterior oblique (LAO) projection. The best working projection varies depending on the distortion of the aortic root in a given patient, but is usually a shallow angulation such as an LAO 10°–20° angulation. A movable-core straight guide wire can be used with a softened tip to probe the aortic valve. Gentle clockwise rotation of the catheter usually moves it more superior along the aortic valve, and it is often possible to align the tip of the catheter with the orifice defined by the calcified leaflets. Using this method, the valve can typically be crossed in less than a minute or two (14).

An extrastiff wire must be used to provide adequate support for passage of the balloon. Placing a large curve on the end of the wire facilitates stability of the wire in the left ventricular apex and diminishes the risks for a wire perforation of the left ventricular apex. It is necessary to curve the wire over the edge of a hemostat or pair of scissors, much in the way that one would put a curl on a piece of wrapping paper ribbon (Fig. 2). After the stiff wire has been passed retrograde across the valve, the diagnostic catheter is removed and an aortic valvuloplasty balloon is passed retrograde across the valve. Considerable forward pressure must be used to keep the balloon in position across the valve while it is being inflated. Because these balloons tend to inflate relatively slowly, maximally dilute saline contrast mixture should be used. A dilution of seven parts saline to one part contrast will minimize the inflation fluid viscosity while still allowing enough radio-opacity to visualize the balloon. The balloon should be inflated and then deflated as rapidly as possible. Using a large syringe, it is not possible to fully distend balloons of this size, and a sidearm stopcock with a “booster” smaller syringe on the side should

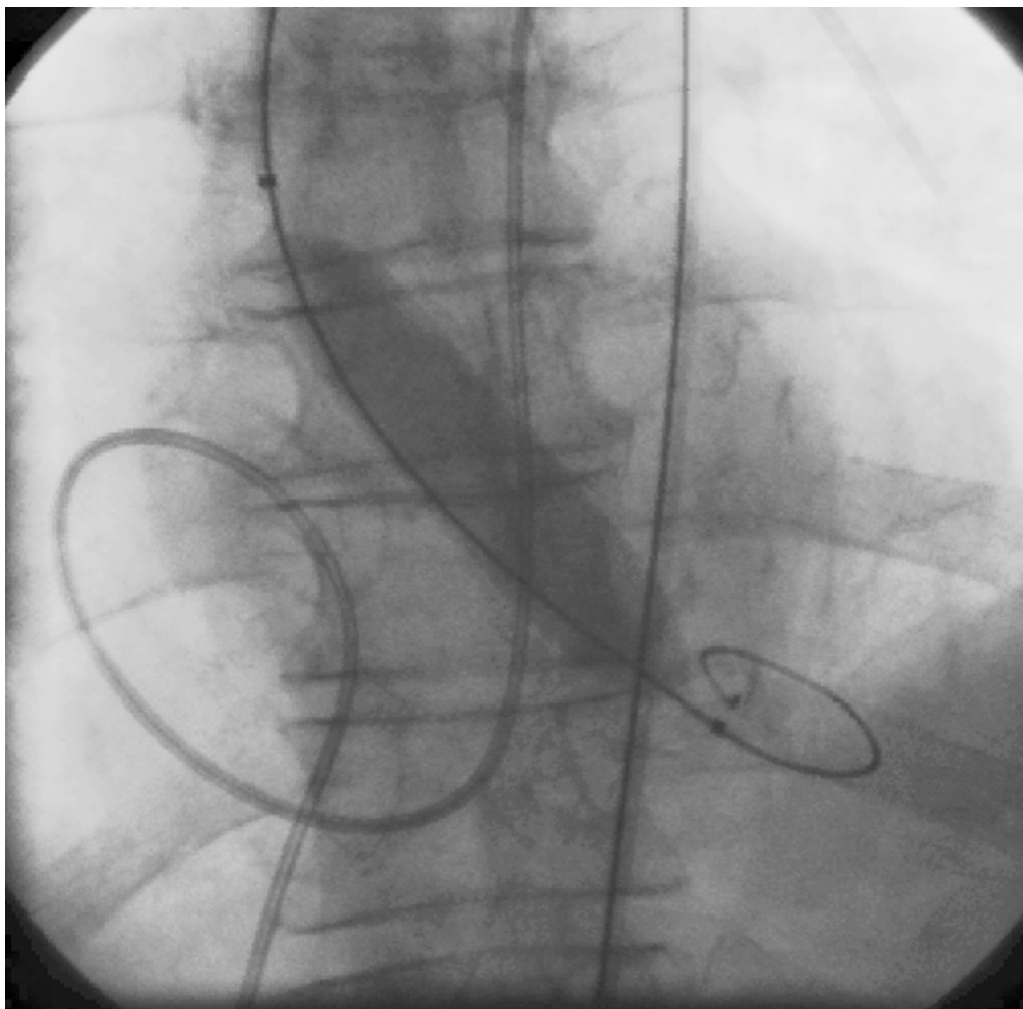


**Fig. 1.** Technique for crossing the aortic valve. Left anterior oblique projection of the aortic root with an aortic stenosis catheter positioned close to the central orifice of the calcified aortic valve leaflets. The white arrow denotes the position of the tip of the aortic stenosis catheter. The small black arrows show the left ventricular side of the aortic leaflet calcifications on either side of the aortic valve orifice. The inset shows the calcified edges of the thickened aortic valve leaflets outlined in white, with the stenotic orifice in between the two white lines.

be used to complete the inflation (18). Typically, a first inflation can be performed without boosting to full inflation volume to test the patient's tolerance of aortic outflow tract occlusion. Second and third inflations can be attempted if the patient appears to tolerate the first inflation. The balloon could rupture in as many as one-third of patients when it is fully inflated.

One major challenge during retrograde BAV is maintaining the position of the inflated balloon within the valve. The force of left ventricular contraction, even in some poorly functioning ventricles, tends to eject the balloon as it is being inflated. Maintaining a stable position requires an extra-stiff guide wire and coordination between the primary operator and the assistant. It sometimes takes repeated attempts to successfully inflate the balloon. When the balloon fully engages the valve, it "locks" into position. This also

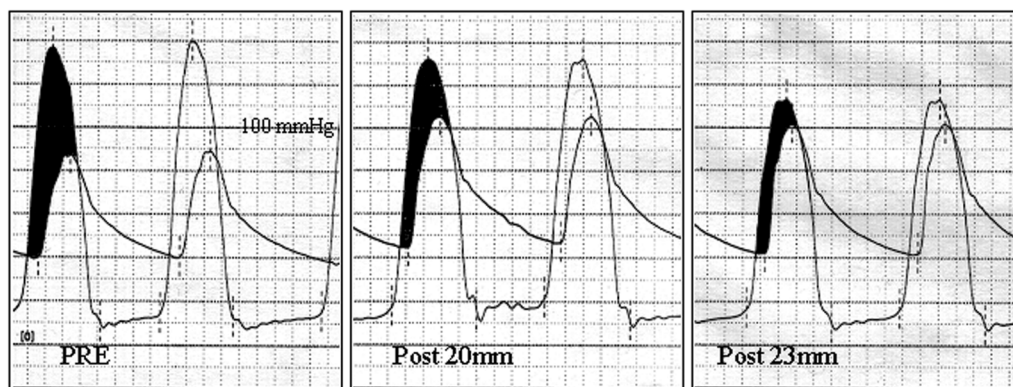




**Fig. 2.** Retrograde aortic valvuloplasty is accomplished by passing a balloon catheter via the aorta across the aortic valve. The wire is looped in the left ventricular apex. The inflated balloon catheter traverses the stenotic aortic valve. A pulmonary artery pressure monitoring catheter is looped in the right atrium. The curl in the guide wire is placed by running the guide wire over the end of the hemostat in a manner analogous to curling a ribbon for gift-wrapping.

clearly demonstrates that the balloon is of adequate size to apply pressure to the leaflets. If the balloon will not maintain a stable position in the valve even when fully inflated, it may be undersized. Cribier has recently described a technique that will facilitate balloon stability. The right ventricle apex can be paced at 200 beats a minute with a temporary pacing wire while the balloon is inflated. This does not prolong hypotension beyond the time that the inflated balloon would ordinarily cause this to occur, and it allows positioning of the balloon in the aortic annulus.

In some cases, arterial pressure recovery after a first balloon inflation is slow, and in the face of poor left ventricular function, it must be determined whether it is safe to continue with additional balloon inflations. Using this approach, there is no good way to monitor the reduction in transvalvular pressure gradient in between balloon inflations.



**Fig. 3.** Hemodynamic changes after aortic valvuloplasty. Before balloon dilatation, a large transaortic valve pressure gradient is noted. The mean gradient is 34 mm Hg. The cardiac output is about 3 L/min, and the aortic valve area is 0.6 cm<sup>2</sup>. After inflations of a 20-mm-diameter balloon catheter, the mean gradient decreases to 20 mm Hg, and the valve area increases to 0.7 cm<sup>2</sup>. A 23-mm-diameter larger balloon is used, and after inflations, the mean gradient is decreased to 9 mm Hg and the valve area increases to 1.0 cm<sup>2</sup>, despite a decrease in cardiac output to 2.84 L/min.

A prototypic procedure involves a test inflation, a second “boosted” inflation, and a third inflation during which the balloon may rupture. It is critical to recognize that only those inflations in which the balloon locks into position in the valve should be considered effective. If the balloon is undersized, it will continue to “watermelon seed” or squirt back and forth in the valve when it is fully inflated. Either an inflation with a larger inflation volume or a larger balloon is necessary in this instance. It is important not to exceed the echocardiographically determined anulus diameter when choosing larger-sized balloons. The vast majority of patients can be successfully treated with a 20-mm-diameter nominal balloon size. Occasional smaller patients may require an 18-mm-diameter balloon. Ten to twenty percent of patients require a 23-mm-diameter balloon for successful single-balloon retrograde dilatation. The risk of aortic cusp avulsion and aortic insufficiency is significantly greater when a 23-mm-diameter balloon is used. A balloon size up to 20 mm in diameter will usually be accommodated by a 12.5 French arterial sheath. The 23-mm-diameter balloon size requires a 14 French arterial sheath. If the balloon is ruptured during balloon inflations, it is unlikely to come back out through the same sheath through which it was introduced. The balloon can be pulled back until it wedges into the sheath, and the sheath and balloon removed as a single unit. A new sheath is then necessary to replace the old one, because the initial sheath will accordion or become deformed by the balloon withdrawal process.

After the balloon is removed, a diagnostic catheter is placed over the existing extra-stiff wire into the left ventricle, the wire removed, and the pressure gradient reassessed. It is typical to have reductions in gradient of about 50%. Gradient reductions may also be caused by depression of left ventricular contractility caused by interference with aortic outflow during the balloon inflations. Occasional patients will develop a low-output state as a consequence. It may take 24–48 h for ventricular function to return to baseline. Thus, a reassessment of cardiac output and recalculation of the Gorlin estimated valve area is the best measure of adequacy of dilatation. Increases in valve area are typically modest. Overall, the valve area will increase from 0.6 cm<sup>2</sup> up to 0.9 or 1.0 cm<sup>2</sup> (Fig. 3).

Retrograde BAV may also be accomplished using a double-balloon technique. Bilateral femoral arterial access is necessary. The aortic valve must be crossed independently from



each femoral arterial access site. This allows smaller sheaths on either side. Two balloons can be inflated simultaneously across the aortic valve. There is less difficulty with balloon slippage. There are no clear guidelines for balloon sizing in this setting. Exceeding the aortic annulus diameter measured by echocardiography with the combined diameter of the two balloons may be risky.

At the completion of the procedure, the arterial sheath is removed. If preclosure with a suture device has been placed, a wire should be passed back into the sheath and the initial knots tied over the wire as the sheath is withdrawn, so that if hemostasis is not successful, the sheath can be replaced. In the event that manual compression is chosen for sheath removal, prolonged compression is typically necessary. A FemoStop is especially useful to accomplish hemostasis in this setting. More rigid mechanical clamps may result in arterial conclusion. Prolonged FemoStop compression may result in deep venous thrombosis, so careful monitoring of the FemoStop is essential.

## ANTEGRADE TECHNIQUE FOR BALLOON AORTIC VALVULOPLASTY

The antegrade technique is performed via a femoral venous access and transseptal puncture (Figs. 4–7 and videos 1–3 on the CD). Compared to the retrograde technique, it provides the advantage of avoiding a large-caliber arterial puncture and has the disadvantages of necessitating transseptal puncture and being a more complex overall technical approach (9,19–21).

The antegrade technique involves establishing transseptal access. Especially for patients with atrial fibrillation, transesophageal echocardiography prior to the procedure is important to rule out the potential for left atrial thrombus. Obtaining vascular access at the outset of the procedure via the left femoral artery, via the left femoral vein for a pulmonary artery catheter for measurement of cardiac output, and via the right femoral vein for transseptal puncture is usual. The right femoral venous access can initially be obtained with a 6 or 8 French sheath, and a suture closure is used to preclose the venous puncture. After a 14 French sheath is placed for passage of the transseptal equipment, the sutures are left outside of the puncture site.

After transseptal puncture, a Mullins sheath is placed in the left atrium. Antegrade passage into the left ventricle is obtained with a single-lumen balloon catheter. A 7 French single-lumen balloon catheter will ordinarily accommodate a wide variety of guide-wire sizes and make the establishment of left ventricular access fairly easy. This catheter can be used for left ventricular pressure measurement to compare to a retrograde transarterial central aortic pressure for gradient measurement. The need to cross the valve retrograde is eliminated, which can save a great deal of time in patients with severely deformed or very tight valves. After the gradient and valve area are confirmed, the single-lumen balloon catheter is advanced into the left ventricular apex via the Mullins sheath and looped in the apex. Further advancement will usually force the balloon catheter to cross the stenotic aortic valve antegrade (Fig. 4). It is sometimes necessary to partially deflate the balloon. In cases when the balloon will not advance around the apex, a curved guide wire can be used to facilitate this step. A straight floppy guide wire such as a Wholey wire is often useful to help advance the balloon tip catheter antegrade across the aortic valve. When the balloon catheter is in the aortic arch, a large-curve guide wire can be used to pass it over the arch into the descending aorta. Simply advancing the balloon catheter will usually result in the catheter becoming lodged in one of the arch vessels. The large-curve guide wire eliminates this entanglement. When the balloon catheter is in the descending aorta, a 0.032-in. extra-stiff guide wire is



**Fig. 4.** To accomplish antegrade aortic valvuloplasty, a catheter is passed via the transseptal route into the left ventricle. A single lumen balloon catheter is looped through the Mullins sheath into the left ventricular apex and passed toward the aortic valve. The aortic valve is then crossed antegrade, and a wire is passed via the venous access through the right atrium, left atrium, left ventricular apex, and into the aorta. The wire can then be snared in the descending aorta and stabilized for antegrade passage of the balloon. The black arrow shows the tip of the Mullins sheath in the left ventricle. The white arrow shows the tip of a single lumen balloon catheter approaching the aortic valve.

passed from the femoral venous access point through the balloon catheter into the descending aorta (Fig. 5). A 10-mm gooseneck snare can then be passed retrograde from the femoral arterial sheath into the descending aorta to snare and fix the guide wire (Fig. 6 and video 1 on the CD). The snare may be withdrawn and the guide wire exteriorized and clamped outside of the femoral arterial sheath. This provides even more support. Advancement of the balloon through the left atrium, traversing the left ventricular apex, and crossing the aortic valve requires this degree of support. Simply parking the 0.032-in. guide wire in the descending aorta is inadequate. Snaring the wire in the descending aorta and leaving the snare is usually adequate, although in some cases the wire will pull out of the snare. It is this latter situation that necessitates exteriorizing the guide wire via the femoral sheath (see video 2 on the CD). Once the wire is looped through the circulation, either advancing or withdrawing it will cause substantial friction. It is critical to advance or withdraw the wire only when it is covered by a catheter. The bare wire may cause enough friction to lacerate the mitral leaflets if it is withdrawn without first covering it with a catheter.

After access is obtained and the wire looped into the descending aorta and snared, a balloon catheter can be passed antegrade via a 14 French right femoral venous sheath through the inferior vena cava, across the transseptal puncture, via the mitral valve and left ventricular apex into the ventricular outflow, and then across the aortic valve. A con-

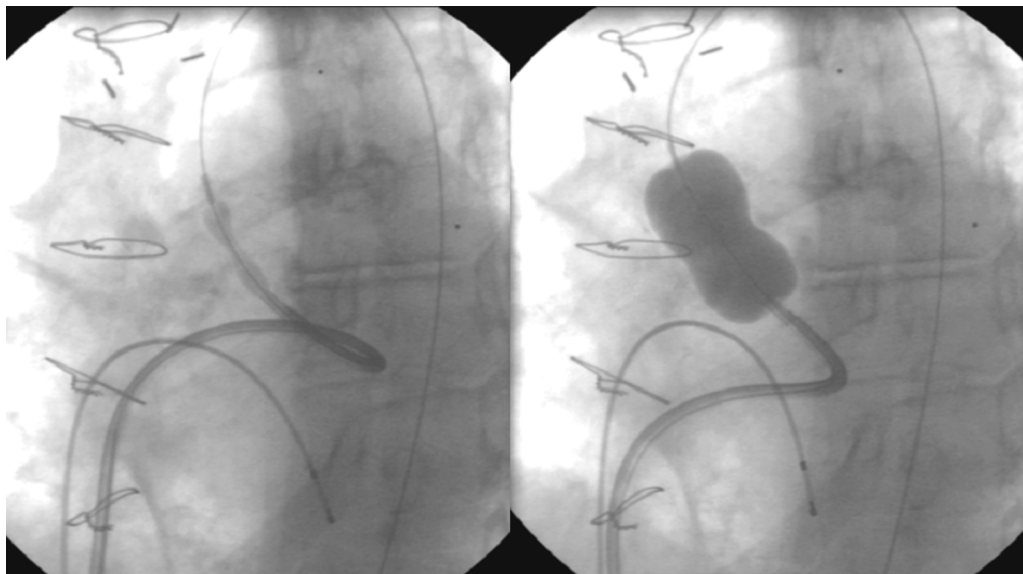


**Fig. 5.** A wire loop can be seen throughout the circulation. In the bottom left-hand corner of the picture, via femoral venous access a Mullins sheath is passed up to the right atrium, through the left atrium, and into the left ventricle. The black arrow denotes the tip of the Mullins sheath near the left ventricular apex. A single-lumen balloon catheter has been passed through the Mullins sheath around the left ventricular apex, across the stenotic aortic valve, and through the aortic arch. A guide wire has been passed through the catheter into the descending aorta and, in this case, into the right femoral artery. The white arrow at the bottom of the picture shows the J-tip of the wire in the right femoral artery. Thus, the wire traverses the entire circulation, beginning in the right femoral vein, coursing through the heart and central aorta, and ending in the femoral artery on the same side.



**Fig. 6.** After the wire is placed in the descending aorta, a gooseneck snare can be passed retrograde through an arterial sheath and used to fix the wire in position. The snare can be left in place to stabilize the wire in the descending aorta or the wire may be pulled through the sheath and exteriorized.

ventional balloon may be used. Twenty-millimeter or 23-mm-diameter balloons will be reasonably accommodated by the 14 French venous sheath. Once the wire is passed through the arterial system and exteriorized on the arterial side, it is also possible to place a large-caliber arterial sheath and use this route for retrograde aortic valvuloplasty. The



**Fig. 7.** After the wire loop has been passed through the circulation, a balloon catheter can be passed antegrade across the aortic valve. In the left-hand panel, an Inoue balloon traverses the left ventricular apex and is straddling the aortic valve. In the right-hand panel, the balloon is fully inflated. Some of the loop in the left ventricular apex has been pulled back to engage the balloon in the valve. As soon as the balloon is deflated, the catheter shaft is advanced to re-establish the wire loop in the left ventricular apex.

problem of balloon “watermelon seeding” in the aortic valve is eliminated with this degree of transcirculatory wire support.

The antegrade approach usually uses an Inoue balloon antegrade via the transseptal venous puncture (Fig. 7 and video 3 on the CD). The balloon tracks well over a 0.032-in. guide wire. When the balloon is inflated across the aortic valve and pulled back, there is no difficulty in controlling its position. The inflate–deflate cycle is much more rapid than a conventional balloon with a much briefer period of hypotension. The size and shape of the balloon conform well to the sinuses of Valsalva. Because the balloon is a volume rather than a pressure balloon, sizing is different than for retrograde aortic valvuloplasty. A 26-mm-diameter balloon is currently the smallest nominal size available in the United States. This balloon can be initially inflated to 22 mm in diameter. If this is tolerated well, 23-, 24-, or even 26-mm-diameter inflations will be well tolerated by most patients. Preprocedure assessment of the annular diameter by echocardiography is helpful in guiding balloon inflation size. After an initial inflation, the balloon may be removed while the wire is left in place. A Mullins sheath can then be passed over the wire into the left ventricle for gradient assessment and further decision-making.

The transcirculatory wire may cause hypotension in some patients. If a loop is not maintained in the left ventricular apex, the wire may prop open the mitral and/or aortic valves and the resulting valvular insufficiency can result in a steady decline in systemic blood pressure. Occasional patients will not tolerate this wire pathway under any circumstances, and the procedure cannot be performed in this manner in that group of patients. If the wire has to be removed, it is important to pass any catheter over it through the left ventricle and aortic arch to reduce friction as the wire is pulled back. A 5F pigtail



or multipurpose catheter can be used, and left in the left ventricular (LV) apex after the wire has been removed to preserve transseptal access and for LV pressure measurement.

At the conclusion of the procedure, the wire must be removed using a catheter to cover it. Simply pulling the bare wire through the circulation will generate a tremendous amount of friction and the wire cannot be easily or safely removed in this manner. A 7F balloon flotation catheter or a 5F diagnostic catheter is passed over the wire via the right femoral vein and into, at least, the ascending aorta. This will allow the snare to be removed. With gentle traction, removal of the wire can be accomplished relatively easily. When the wire has been pulled back into a diagnostic catheter, the catheter may be withdrawn until it is in the left ventricle. This will maintain the antegrade transseptal access and leave a catheter in a good position for measurement of a final gradient without interference from the wire. Assessment of the final transaortic valve gradient with the wire completely removed is necessary, because the wire will often cause a false diminution of the transaortic valve pressure gradient, sometimes with the appearance of no gradient whatsoever, even in the face of significant residual aortic stenosis.

Initial experience with this antegrade approach has yielded larger valve areas than can be obtained with the single-balloon retrograde technique (19). The potential mechanism for this finding is the distention of the distal end of the Inoue balloon, which conforms well to the sinus of Valsalva. The aortic leaflets are distended into the sinus by the distal end of the Inoue balloon. In contrast, a conventional balloon has straight sides and will achieve no more than a diameter smaller than the inner diameter of the anulus and, substantially, less than the sinus of Valsalva.

## COMPLICATIONS OF BALLOON AORTIC VALVULOPLASTY

A number of management problems are common during BAV (Table 3). Predominant among them is hypotension. This could result from left ventricular depression from balloon occlusion of the outflow tract, bleeding from the large caliber femoral access site, perforation of the left ventricle as a result of wire passage or the sharp tip of the balloon catheter, and aortic insufficiency resulting from damage to the leaflets or anulus during the course of balloon inflations. During balloon inflations, blood pressure drops precipitately and it is important to withdraw the balloon from the valve orifice before the balloon is fully deflated to allow forward cardiac output to be restored. At the same time, it is important to be cognizant that the large size of the balloon may obstruct the arch vessels if it is left overlying the brachiocephalic or carotid origins. In cases where the hemoglobin is low prior to the initiation of the procedure, transfusion so that a reasonable starting level of hemoglobin is present is important, as is a type and screen so that blood can be readily available in the event of bleeding.

Bradycardia is also relatively common. This may result from abrasion of the septum by catheters or conducting system injury as the rigid aortic anulus is distended against the atrioventricular conducting system during balloon inflations. In patients with underlying bundle branch block or atrioventricular block, placement of a temporary pacemaker is important so that bradycardia can be managed rapidly. Occasionally, patients will develop heart block and ultimately require a permanent pacemaker. Major complications are encountered as a consequence of the severity of illness and multiple comorbid conditions typical in the BAV population. Death in the hospital occurs in 5–8% of patients (22). The majority of these deaths occur outside of the cardiac catheterization laboratory as a consequence of other complications of the procedure. One or two percent of patients will expire

**Table 3**  
**Common Management Problems**

Bradycardia
Conducting system injury
Vagal
Perforation
Hypotension
LV depression
Bleeding
Perforation
Aortic insufficiency
Sheath injury

in the catheterization laboratory because of LV power failure after balloon inflations and failure to recover left ventricular function or from mechanical complications related to trauma from balloons. Bleeding is the most common complication. As many as one-fourth of patients require transfusion, and, in some reports, 5–7% require surgical vascular repair for femoral access complications (23). The use of suture closure has resulted in less frequent transfusions and shorter lengths of stay. The preclosure technique of placing a small 6 or 8 French sheath, then preloading percutaneous suture closure and not tying knots, followed by placement of the large sheath, and, ultimately, removal of the sheath and closing of the suture knots at the end of the procedure is well described. In one report, this technique completely eliminated the need for transfusions and surgical vascular repair (16).

Cardiac perforation from wires or balloons is an important complication that must be considered whenever hypotension occurs in the periprocedure timeframe. Liberal use of echocardiography in the catheterization laboratory or recovery area is critical to recognize and treat pericardial effusion and tamponade at the earliest possible juncture (Table 4).

## RESULTS OF BALLOON AORTIC VALVULOPLASTY

The acute hemodynamic results of BAV are often modest. The cardiac output increases a small but statistically significant amount. Decreases in transvalvular pressure gradient range from 30% to 50%. Using the single-balloon retrograde technique, it is uncommon to have residual gradients of less than 10 mm Hg in patients with preserved cardiac output. Increases in valve area typically are from preprocedure levels of 0.6 cm<sup>2</sup> to postprocedure levels of 0.9 cm<sup>2</sup> using the retrograde single-balloon approach. With the antegrade Inoue balloon approach, a mean postprocedure valve area of 1.2–1.4 cm<sup>3</sup> is common, and post-procedure transvalvular pressure gradients less than 10 mm are frequent. Most patients are clinically improved for 12–18 mo (24).

The long-term results of BAV have been described. Comparisons of survival in this patient group with untreated patients with severe aortic stenosis suggest that there are no survival benefits attributable to the procedure (25–27). Patients who achieve good hemodynamic results typically will be clinically improved, sometimes with minimal improvements in Gorlin valve area. Most patients have sustained clinical improvement for 1–1.5 yr. The major goal of this procedure is palliation of symptoms. It is unwise to offer BAV to patients with severe aortic stenosis who are only mildly symptomatic, because the procedure has significant risks and offers only symptomatic benefits. For

**Table 4**  
**In-Hospital Complications of Aortic Valvuloplasty**

Cardiac death	5–8%
Noncardiac death	1–2%
Embolism	2–5%
Myocardial infarction	1–2%
Tamponade	<1%
Shock	1–3%
Cardiac surgery	1%
Transfusion	23%
Vascular repair	5–7%

those patients who are severely debilitated, the procedure improves quality of life tremendously. Patients are often made relatively functional at a time when this is all that can be offered to them.

### LIMITATIONS OF BALLOON AORTIC VALVULOPLASTY

A number of technical and procedural issues limit the utility of this procedure. The retrograde approach requires crossing the aortic valve retrograde, which may not be possible in some patients. Large-caliber balloons necessitate large-size vascular access for either the antegrade or retrograde routes. Improvements in balloon technology have been slower for valvuloplasty than for coronary equipment because of the smaller patient population served by these devices.

Restenosis remains the major limitation of the utility of this procedure. Histopathologic studies have demonstrated the mechanism of successful BAV to be fracture of the calcific nodules seen in the aortic valve leaflets (28). The nodules are typically amorphous calcium encased in a fibrotic capsule on the superior or aortic arch side of the leaflets. The pressure of balloon inflation, which causes cracks or hinge points in these nodules, allows greater mobility of the valve leaflets. These nodules refibrose, and the cracks or hinge points are obliterated by this healing process. Animal studies have demonstrated less rapid calcification of valve leaflets in a setting where calcium blockers are used (29). More recently, the inflammatory lesion thought to contribute to the progression of aortic stenosis has responded to therapy with statin drugs (30). It remains to be seen whether medical therapy might slow the occurrence of restenosis after BAV.

The most promising light on the horizon that would overcome these severe limitations is the development of percutaneous aortic valve replacement. The basic techniques necessary to accomplish this procedure are similar to those used in BAV and many create a new emphasis on BAV as a predilatation strategy. Initial human results are encouraging (31). This latter development would also overcome the obvious limitation imposed on balloon catheter therapy by regurgitant lesions (Table 5). Regurgitant lesions make the utility of BAV impossible in a significant number of patients. Percutaneous valve replacement would be an ideal therapy in this setting.

### BALLOON PULMONIC VALVULOPLASTY

Pulmonic stenosis is synonymous with a congenital etiology. The pulmonic valve is unlikely to be affected by acquired cardiovascular diseases. Most patients present in

Table 5  
Limitations of Balloon Aortic Valvuloplasty

Retrograde access to LV
Hemodynamic assessment
Low gradient/low output
Large-caliber balloons
Slow inflate–deflate cycle
12 to 14 French femoral arterial access
Restenosis
Fibrosis of cracks/fissures made by balloon
Regurgitant lesions

Table 6  
Intervention for Pulmonic Stenosis

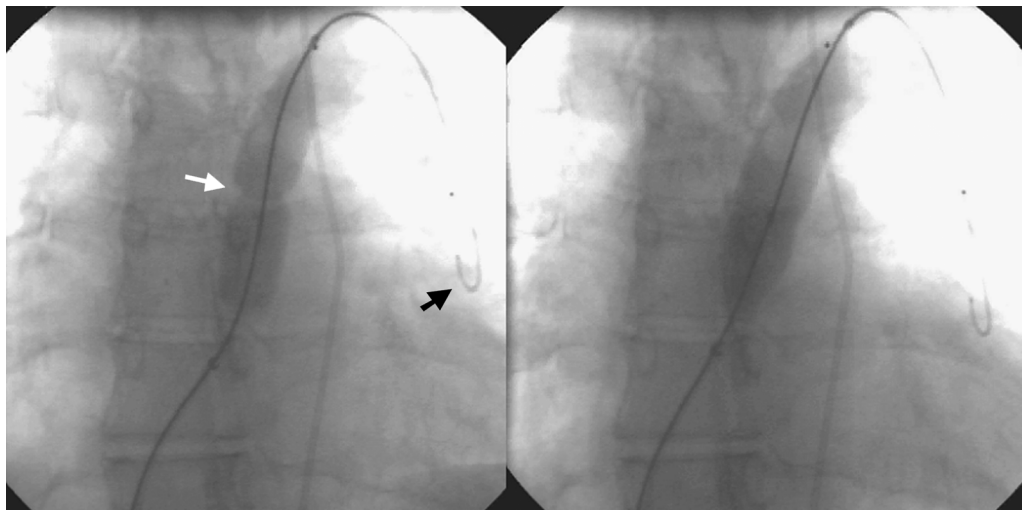
Class I
Exertional dyspnea, angina, syncope, presyncope
Asymptomatic, normal cardiac output, peak gradient >50 mm
Class IIa
Asymptomatic, normal cardiac output, peak gradient 40–49 mm
Class IIb
Asymptomatic, normal cardiac output, peak gradient 30–39 mm
Class III
Asymptomatic, normal cardiac output, peak gradient <30 mm

childhood. Symptoms are unusual until adolescence or adulthood. Adults usually present with symptoms of fatigue or dyspnea.

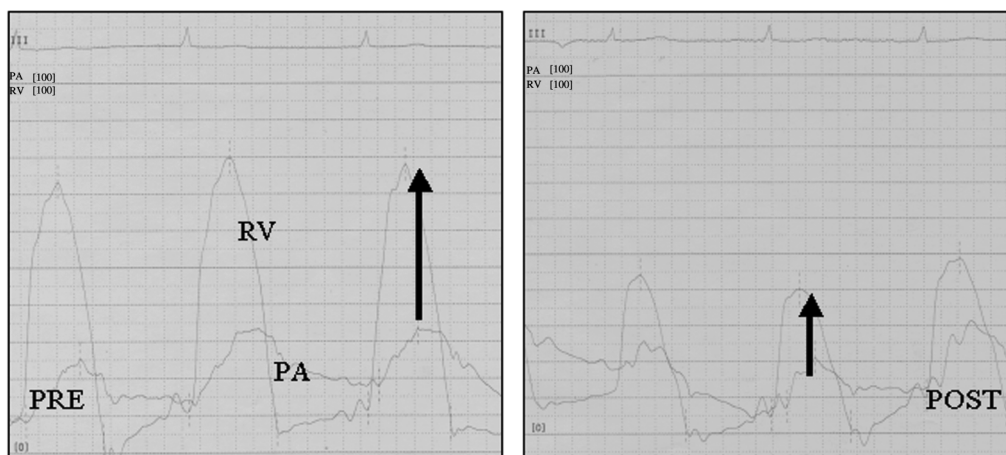
Balloon pulmonic valvuloplasty (BPV) is the treatment of choice for these adult patients and has excellent long-term results. The approach can be considered curative. The AHA/ACC Task Force recognizes valvuloplasty for pulmonic stenosis as a Class I indication for symptomatic patients with dyspnea, angina, syncope, or presyncope, as well as those who are asymptomatic with peak transpulmonic gradients over 50 mm Hg (Table 6) (6).

Long-term studies of the results of valvotomy for pulmonic stenosis in children, adolescents, and adults have shown excellent results. In a large study on the natural history of congenital heart defects, patients were followed for up to 25 yr after BPV (32). The probability of survival was similar to that of the general population and the vast majority of patients remained asymptomatic. Reoperation was rarely necessary for those treated in childhood. Patients with gradients less than 25 mm did not experience an increase in gradient. Patients with gradients greater than 50 mm clearly required therapy. For children in the intermediate zone, there was some uncertainty regarding a best recommendation for treatment. The probability of 25-yr survival was 96%. The probability of survival was less than 80% in a subgroup of patients more than 12 yr old with cardiomegaly. Less than 20% of the patients managed medically for low gradients required a valvotomy.

Balloon pulmonic valvuloplasty for pulmonic stenosis in adolescents and adults has also been well described. In one study with a mean follow-up of 7 yr, the vast majority



**Fig. 8.** Balloon pulmonic valvuloplasty is accomplished by antegrade transvenous passage of a wire across the stenotic pulmonary valve into the left pulmonary artery. In the left panel, a balloon catheter is inflated across the stenotic pulmonary valve. The white arrow shows an indentation in the balloon caused by the stenosis. The black arrow shows the tip of the guide wire anchored in the left distal pulmonary artery. In the right-hand panel, the indentation in the center of the balloon has been relieved as the balloon is fully inflated to treat the stenotic pulmonary valve.



**Fig. 9.** Hemodynamics with pulmonic valvuloplasty. Before valvuloplasty, the right ventricular pressure is 80 mm Hg. The black arrow denotes the large gradient between the pulmonary artery and the right ventricle across the stenotic pulmonary valve. After valvuloplasty, the gradient is dramatically diminished, again shown by the black arrow. Although the pulmonic pressure has remained relatively constant, the right ventricular pressure has fallen dramatically. Both panels are shown on a 100-mm Hg scale.

of patients remained free of symptoms throughout the study period (33). Incompetence of the pulmonic valve was noted in 7 of 53 (13%) after balloon valvuloplasty, but had disappeared at follow-up in all of these patients. The gradient decreased on average from over 90 mm Hg to less than 40 mm Hg at the time of the procedures. At late follow-up,



there was a further decrease in the gradient, probably as a result of regression of right ventricular infundibular hypertrophy.

The technique of BPV involves the passage of a conventional or Inoue balloon catheter via the femoral route antegrade through the right atrium and right ventricle, and across the pulmonic valve (Fig. 8). The wire may be “anchored” in the left pulmonary circulation. Echocardiography to assess the pulmonary valve annular diameter prior to BPV is an important part of planning the procedure. A balloon-to-annulus ratio between 1.1 and 1.3 is usually selected. One or two balloon inflations are usually sufficient to result in elimination of the stenosis. Typical hemodynamic results are shown in Fig. 9.

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