Pediatric Interventions

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A growing list of transcatheter interventions is now available for treating patients with congenital and acquired heart disease. Among these procedures are creation of interatrial defects by balloon and blade septostomy, balloon dilation of stenotic vessels and valves, and closure of unwanted intracardiac and extracardiac defects and vessels. This chapter focuses on several interventions: balloon pulmonary and aortic valvuloplasty, angioplasty of aortic coarctation and of branch pulmonary artery stenosis, coil embolization of unwanted vessels including patent ductus arteriosus (PDA), device closure of atrial septal defects (ASDs) and ventricular septal defects (VSDs), and implantation of intravascular stents in patients with congenital heart disease.

BALLOON DILATATION VALVULOPLASTY

Balloon valvuloplasty (alternatively called balloon valvulotomy) is discussed in Chapter 26, but this section deals with application of this technique in the (predominantly pediatric) population with congenital heart disease. As with adult valvuloplasty, choosing the most appropriate balloon catheter is important not only to maximize the likelihood of successful dilation but also to avoid or minimize complications. The most common type consists of a single, cylindrical balloon mounted on a shaft that is delivered to the stenotic lesion over a guidewire. Although this type of catheter distributes wall stress equally around the circumference and folds to a relatively small collapsed profile, it tends to completely obstruct blood flow during inflation. Catheters with two or three balloons mounted on the same shaft help overcome such obstruction to flow, but their failure to distribute wall stress evenly may engender a variety of other clinical consequences. Other specialized balloons include Inoue's unique balloon for dilating mitral stenosis and a variety of balloons designed for coronary angioplasty, such as those mounted directly on a guidewire (see Chapter 23).

It is important to know the maximal pressure to which a balloon can be inflated before rupture. This pressure varies with the balloon material and inversely with the balloon diameter. High pressures are rarely needed when dilating valves but are essential in some applications, such as dilation of most pulmonary artery stenoses. Balloons are designed to rupture and tear longitudinally. If the tear is transverse, as occurs most commonly when the balloon ruptures on calcium, the distal half of the balloon will fold back on itself, making removal difficult. For this reason and to minimize the risk of vessel rupture, which is more likely to occur when the balloon ruptures, intentional balloon rupture should generally be avoided by limiting the inflation pressure to the rated burst pressure. A pressure gauge should be used to monitor inflation pressure when dilating lesions that require high pressure.

Balloons are manufactured to achieve certain maximal diameters. The actual inflated diameter varies depending on inflation pressure and balloon compliance. Balloon length, by convention, refers to the cylindrical portion of the balloon, excluding the taper at either end. Long balloons are more stable during inflation and easier to keep positioned as the heart contracts and ejects. As the balloon straightens during inflation, however, the ends of a long balloon may damage adjacent structures. Examples include damage to the right ventricular outflow tract when dilating valvar pulmonary stenosis. Therefore, 2- or 3-cm balloons are used for most lesions. An exception would be aortic valvuloplasty in older patients, where use of a long balloon is necessary to avoid its ejection from the valve orifice during inflation. The balloon profile, defined as the diameter of the deflated balloon, can be several French sizes larger than the shaft, depending on balloon size and material. High-profile balloons are more likely to damage vessels at the entry site and may be difficult to pass across tight stenoses. Balloons also vary in terms of the length of the shoulders at each end of the balloon. Although a longer taper may make entry at the groin easier, the taper when combined with a long distal tip may make centering of the balloon in the lesion more difficult. For example, when
the stenotic orifice in mitral stenosis is nearer the left ventricular apex, a long taper and tip may prevent the balloon's being advanced far enough to allow dilation of the stenosis.

Most valvuloplasty balloons are mounted on shafts between 4F and 9F. A large shaft offers the potential advantages of increased stiffness, use of a larger guidewire, and a larger inflation/deflation lumen. However, a large shaft is more likely to damage the femoral vessels, which is the most common complication in pediatric patients undergoing balloon dilation. We therefore generally choose the smallest shaft size available with the desired balloon diameter. Stiffer shafts make groin entry easier and help to stabilize the balloon position during inflation, but may make following the guidewire around sharp turns more difficult. The tip of the catheter, the part of the shaft that extends beyond the balloon, varies in length and degree of tapering. Although longer tips with a more gradual taper are easier to pass through the groin puncture site, the long tip may prevent proper positioning of the balloon. It is also important to have the catheter lumen closely match the diameter of the guidewire to prevent entrapping of tissue at the tip of the catheter.

Two or more balloons may be positioned and inflated simultaneously to achieve a larger effective diameter than is possible with a single balloon. We use Yeager's formula (5) for calculating the effective combined diameter of two balloons.

**Percutaneous Balloon Pulmonary Valvuloplasty**

Reports of the use of blade or balloon catheters to perform pulmonary valvuloplasty appeared as early as 1953. However, the static balloon technique, reported by Kan et al., in 1982, was the first to be applied widely. Subsequent results (9–12) have demonstrated the safety and effectiveness of this technique and have established it as the treatment of choice for children and adults with isolated pulmonary valve stenosis (see Chapter 26).

**Technique**

A complete precatheterization Doppler echocardiogram defines valve morphology, measures the pulmonary annulus, and rules out associated defects. With the patient under routine sedation, a sheath is placed percutaneously in the femoral vein and a balloon-tip end-hole catheter is used to measure right-sided heart oxygen saturations and pressures. After placement of a small pigtail catheter in the femoral artery for monitoring of the arterial pressure, the patient is heparinized. The gradient across the pulmonary outflow is measured, and the location of the valve is defined with the use of fluoroscopy and a right ventriculogram in the anteroposterior and lateral projections. The pulmonary annulus is measured at the hinge points of the valve, and the balloon diameter is chosen to be 1.2 to 1.4 times that of the annulus (Fig. 28.1). Animal studies (4) and results in patients (9) have demonstrated that the use of such oversized balloons is safe and yields improved results. When the annulus is larger than 20 mm, such overdilation usually requires simultaneous inflation of two balloons.

**FIG. 28.1.**

The pulmonary valve annulus diameter measured from angiograms versus patient age.

An end-hole catheter is advanced to the distal right or left pulmonary artery, and the venous catheter and sheath are removed over an exchange wire and replaced with a sheath large enough to accommodate the balloon dilatation catheter. Once the balloon has been centered across the pulmonary valve, it is inflated rapidly until the “waist” disappears and then deflated and withdrawn to the inferior vena cava. Video playback is reviewed to ensure proper balloon position and size.

A pressure pullback is performed to measure the transvalvar gradient and to look for a subvalvar gradient that sometimes develops after dilation. A residual transvalvar gradient of more than 20 to 30 mm Hg is unusual and suggests improper position of the balloon during dilation, improper balloon size, or a dysplastic valve. If the subvalvar gradient is more than 30 mm Hg, a right ventriculogram is performed to evaluate the location and extent of subvalvar obstruction. The cardiac output is also remeasured to calculate valve area.
Patients with critical pulmonary stenosis may not tolerate the prolonged presence of a catheter across the valve because of further restriction of functional valve area. In patients with systemic right ventricular pressure, we perform the initial right ventriculogram before crossing the valve. If the patient deteriorates after the valve has been crossed, the catheter is removed without measuring a gradient, and only the exchange wire is left in place. In these patients, a relatively small balloon is frequently used for the initial dilation, followed by an oversized balloon for definitive dilations.

Neonates presenting with critical pulmonary stenosis are commonly cyanotic due to right-to-left shunts at the atrial level and are dependent on a patent ductus for pulmonary blood flow. Because of the atrial and ductal shunts, both systemic and pulmonary blood flows tend to be maintained during balloon inflation. Crossing the valve can be difficult, however, because of both the small, hypertrophied right ventricle and the pinhole opening in the valve. We attempt to cross the valve with a balloon-tip end-hole catheter, but if this is unsuccessful, we use a 3F or 4F preformed catheter (60° to 90° short bend at the distal end). This catheter is manipulated to the right ventricular outflow tract. If it does not cross the valve directly, a 0.018-inch torque-control guidewire is used to probe the outflow tract until the valve is crossed. Once the instrument is across the valve, we dilate initially with a small balloon and then with a balloon 20% to 40% larger than the annulus.

Results

Excluding neonates, the first 66 patients to undergo balloon pulmonary valvotomy at our institution included 9 patients who had undergone a previous surgical valvotomy—usually for critical pulmonary stenosis as neonates. In these nine patients, the transvalvar gradient was decreased from an average of 60 to 19 mm Hg using a balloon-to-annulus ratio of 1.24, with no significant complications. Of the remaining 57 patients, 54 valves were dilated successfully with a balloon-to-annulus ratio of 1.27. The transvalvar gradient decreased from 74 to 15 mm Hg and the right ventricular pressure from 101 to 50 mm Hg with no significant change in cardiac output. The postdilation transvalvar gradient in the 54 successful cases was less than 30 mm Hg regardless of the predilation gradient or age. Small subvalvar gradients were common, but 4 of 54 patients had subvalvar gradients of more than 30 mm Hg (45, 60, 75, and 80 mm Hg). The subvalvar gradient resolved in each case within 1 year. There were four failures in three patients with severely dysplastic valves. No cases of significant restenosis have been identified. The only significant complication occurred early in the series in a patient who developed transient complete heart block.

In 35 consecutive neonates at our institution with critical pulmonary stenosis, the valve was crossed and dilated in 34. The transvalvar gradient decreased from an average of 63 to 24 mm Hg, and the right ventricular-to-systemic pressure ratio (systolic) decreased from 1.5 to 0.8. The balloon-to-annulus ratio for the largest balloon used was 1.25. Complications included perforation and tamponade in two patients and one death due to overwhelming sepsis. During follow-up, six patients were redilated, five successfully. An additional two patients had surgery for a dysplastic valve. Only three patients had gradients greater than 30 mm Hg, and all gradients were less than 50 mm Hg.

Our results, combined with those from other centers, demonstrate that balloon pulmonary valvotomy, using oversized balloons, is safe and effective in relieving pulmonary valve stenosis in all age groups and in patients who have undergone surgical valvotomies. We currently attempt balloon pulmonary valvotomy in any patient with a transvalvar gradient greater than 40 mm Hg and in neonates with critical pulmonary stenosis.

Percutaneous Balloon Aortic Valvuloplasty

Balloon aortic valvuloplasty was first reported in 1983 in a child with congenital aortic stenosis (13). It has been performed since then in large numbers of patients with both congenital and acquired stenoses (14–18). Although initial results in adults with calcific stenosis were encouraging, the modest relief of stenosis achieved, combined with a high rate of early restenosis, has limited its use in this group of patients. Most adult centers now prefer valve replacement, reserving balloon valvuloplasty for patients who are high-risk candidates for surgery. In most patients with congenital aortic stenosis, the alternative to balloon dilation is a surgical valvotomy. Because the results of balloon valvuloplasty appear comparable to those obtained by such surgery (in terms of relief of obstruction and restenosis rate), we continue to use balloon dilation in patients with congenital aortic stenosis.

Technique
With the patient under routine sedation, a femoral vein and artery are entered percutaneously and the patient is heparinized. The venous catheter measures right-sided heart pressures and cardiac output before and after dilation. In older patients, aortic valves can be dilated from the femoral vein using a transseptal approach, but the retrograde approach via the femoral artery remains the most common technique. We start with an appropriately sized sheath in the artery and a pigtail catheter 1F size smaller than the sheath. This allows simultaneous pressure measurements through the sheath and pigtail. Any intrinsic gradient is determined by comparing the pressure measured through the pigtail catheter in the iliac artery and then in the ascending aorta with the pressure recorded through the side-arm of the sheath.

The easiest technique for retrograde crossing of the stenotic aortic valve is to advance the soft end of a straight wire out of a pigtail catheter and use it to probe for the valve orifice (see Chapter 4). This probing need not be entirely random if precatheterization echocardiograms have defined the valve morphology and position of the orifice. In congenitally stenotic valves, even unicommissural valves, the commissure that lies between the left and noncoronary cusp is the one that is almost always open. Therefore, during probing with the wire, the pigtail catheter is manipulated to direct the wire posteriorly and to the left. The probing must be done gently to avoid perforating a cusp or damaging the coronary arteries. When the left ventricle is entered, a transvalvar gradient is measured by simultaneously recording pressure from the pigtail and the femoral sheath. If the valve was easy to cross, a pressure pullback is performed, followed by an aortogram for aortic regurgitation. A left ventriculogram is performed, and the aortic annulus is measured at the hinge points of the valve.

The balloon diameter is chosen to be 75% to 90% of the annulus diameter (Fig. 28.2). Animal and clinical studies \(^{(19),(20)}\) demonstrate that aortic valvuloplasty with a balloon-to-annulus ratio greater than 1.0 is more likely to be associated with damage to the outflow tract and increased aortic regurgitation. Double balloons are used when the annulus is larger than 22 mm. The pigtail catheter is exchanged for the dilatation catheter over an exchange wire, and the balloon is flushed with carbon dioxide and dilute contrast material in the thoracic aorta. The balloon is centered across the valve, inflated and deflated rapidly, and pulled back to the descending aorta. Videotapes are reviewed to check balloon size and position.

**FIG. 28.2.**

The aortic valve annulus diameter measured from angiograms versus patient age.

The gradient and cardiac output are remeasured after dilation, and an aortogram is performed to look for aortic regurgitation. If the residual gradient is greater than 55 mm Hg and an aortogram shows no more than mild regurgitation, a larger balloon is used. A final pressure pullback and aortogram are then performed.

It can be difficult to keep the inflated balloon positioned in the valve against the force of left ventricular ejection. A stiff catheter shaft, a long balloon, and a stiff or extra-stiff exchange wire help stabilize the position. In addition, balloon ejection is counteracted by advancing the catheter so that it lies along the top of the aortic arch rather than around the underside of the arch. Finally, the double-balloon technique, which does not totally obstruct flow, may make it easier to maintain balloon position.

Although the overall approach is similar to that used in older patients (see Chapter 26), several special techniques are useful in neonates. The umbilical artery usually can be used in the first week of life. Catheter manipulation is more difficult from the umbilical artery, but its use avoids damage to the femoral artery. In addition, many centers use the carotid artery, an approach that makes crossing the valve very easy. As with older patients, a transseptal approach can be used, from either the femoral or the umbilical vein. To cross the aortic valve retrograde, a 3F or 4F pigtail catheter with the tail partially cut off is used to direct the guidewire posteriorly and leftward toward the open commissure. Because neonatal valves are very easy to perforate, we use a 0.018-inch torque-control guidewire with a very soft tip. Any difficulty in getting the pigtail or balloon catheter to follow the wire across the valve suggests cusp perforation.

**Results**
The results and complications in the first 149 patients are considered in two groups: neonates (younger than 1 month) and older patients. In the 122 older patients, the transvalvar gradient was reduced by 56%, from 76 to 33 mm Hg. The valve area index increased 51%, from 0.53 to 0.80 cm²/m² of body surface area. The percent gradient reduction was unrelated to age (1 month to 39 years), history of prior surgical valvotomy (n = 18), predilation gradient, or final balloon-to-annulus ratio (mean, 0.98; range, 0.71 to 1.33). Aortic regurgitation (on a scale of 0 to 5) increased from grade 0.57 to grade 1.18. We have previously shown an inverse relation between gradient reduction and increased regurgitation (14). The risk of a greater than 1 grade increase in regurgitation rose from 11% (6/55) when the balloon-to-annulus ratio was less than 1.0 to 30% (6/20) when the ratio was greater than 1.0. Approximately 10% to 15% of patients have at least grade 3/5 aortic regurgitation after dilation. Complications involving the femoral artery have decreased with the availability of lower-profile balloons. Transient left bundle branch block occurred in 15% and ventricular arrhythmias requiring cardioversion in 3% (14). Follow-up analyses have shown that 50% of patients are free from reintervention at 8 years and survival is 95% (18).

Neonates are a different group in terms of results and complications (21). In the first 27 consecutive neonates with critical aortic stenosis at our institution, the valves were dilated regardless of clinical condition, valve morphology, left ventricular size or function, or degree of mitral regurgitation. They ranged from 1 to 30 days of age and from 2.2 to 5 kg. Unicommissural valves were present in 17 and bicommissural valves in 10. The left ventricular volume was greater than 80% of predicted normal in 16, 60% to 80% of normal in 7, and less than 60% of normal in 4. Using a balloon-to-annulus ratio of 0.90, the peak systolic ejection gradient was reduced from 58 to 27 mm Hg and the left ventricular end-diastolic pressure also was reduced significantly. New aortic regurgitation developed in 11 patients; it was mild in 8 and severe in 3 who died. However, because of poor ventricular function and the common presence of a PDA with right-to-left flow, gradients are an unreliable indicator of the degree of obstruction and outcome. If failure is defined as death (n = 9) or need for stage I palliation for hypoplastic left heart syndrome (n = 2), there were 11 failures, with 9 occurring in the 11 patients with left ventricular volumes less than 80% of normal. It is clear that not all patients are suited to valvotomy alone, whether by a surgical or balloon technique. Further analysis of a group of patients with critical aortic stenosis undergoing surgical valvotomy or balloon dilation has led to a scoring system based on echocardiographic measurement of left-sided structures that can be used to choose those patients who are most likely to survive with two ventricles (22). Other patients are converted to single ventricles using the stage I palliation for hypoplastic left heart syndrome.

We currently dilate congenitally stenotic aortic valves in patients who have transvalvar gradients greater than 55 mm Hg and no more than mild aortic regurgitation and in neonates with critical aortic stenosis who have adequate left heart size.

PERCUTANEOUS BALLOON ANGIOPLASTY

Coarctation and Postoperative Aortic Obstructions

Percutaneous balloon angioplasty of coarctation was first described in 1982 (23) and has since been used in large numbers of patients with native coarctation (unoperated) and postoperative recoarctation (24–33). A study of experimental coarctation in lambs (34) demonstrated that relief of obstruction occurs by tearing of the intima and media. Short- and long-term complications seen in that study, including perforation resulting in death and late aneurysm formation, have now been described in patients.

Technique

With the patient under routine sedation, the femoral vein and artery are entered percutaneously and the patient is heparinized. Coarctations can be dilated via an antegrade, transseptal approach, but the retrograde femoral arterial approach is preferred for most patients. Right- and left-sided heart hemodynamics are measured (including cardiac output), and a careful pullback is performed to localize gradients. Biplane aortography is performed in either
anteroposterior and lateral or right anterior oblique and long axial oblique projections. More than one aortogram may be required to profile the lesion. The diameters of the narrowest area of coarctation and of the normal proximal and distal aorta are measured.

For postoperative recoarctations, the balloon is chosen to be approximately 2.5 to 3 times the narrowest area but not greater than 1.5 times the normal proximal or distal aorta. For native coarctations, the balloon is commonly chosen to be equal to the diameter of the aorta at the isthmus. Relatively long balloons can be used in distal coarctations, but short balloons should be used in the transverse arch. High inflation pressures are often required in recoarctations. The balloon dilatation catheter is advanced through a sheath over an exchange wire and purged with carbon dioxide and dilute contrast material in the descending aorta. It is centered across the coarctation, inflated until the “waist” disappears or to maximal inflation pressure, and deflated. Video playback is reviewed to ensure proper position and balloon size. The balloon catheter is exchanged for a pigtail catheter, which can be used to measure a pullback gradient by using the single pigtail over the wire with a side-arm adaptor, or by placing a second arterial line. The dilated area should be crossed only over a guidewire because of the danger of perforation. An aortogram is performed after dilation to determine the diameter of the narrowing and to detect tears, ruptures, or dissections. If significant obstruction remains despite disappearance of the balloon “waist” during inflation, a larger balloon can be used. Chest pain is common during balloon inflation, but persistent pain suggests aortic rupture or dissection.

Results

Of the first 64 angioplasties at our institution, in 62 patients ranging in age from 3 days to 67 years, 5 were native and 59 were postoperative coarctations. The gradient was reduced from 39 to 13 mm Hg, and the diameter of the lesion was increased from 4.9 to 8.2 mm. Procedures are considered successful if the gradient is reduced by more than 50% and the diameter is increased by more than 30%. Based on these criteria, 54 (83%) of these procedures were successful. The balloon-to-lesion ratio was 3.0 for the successful group and 1.6 for the failures. The failures had significantly lower predilation gradients, had significantly larger predilation lesion diameters, and were significantly older. Because of the relatively large predilation diameters in the failed group, use of larger balloons in an effort to improve gradient reduction, would risk injuring the normal aorta (35). Results in recoarctations are unrelated to the type of previous surgery. The success rate for patients with restenosis after repair of interrupted aortic arch or hypoplastic left heart syndrome is similar. In patients with hypoplastic left heart syndrome, dilation is commonly performed via the femoral vein.

The most common complication is loss of the arterial pulse, and one baby died after iliac artery rupture and a retroperitoneal hemorrhage. The incidence of femoral artery injury has decreased with the availability of lower-profile balloons. The only other significant short-term complication in our series was an aortic dissection that occurred immediately after dilation in a 67-year-old woman with a native coarctation. During follow-up, three patients were found to have small, asymptomatic aneurysms (two of these procedures were performed after surgery for interrupted aortic arches, and one was a dilation of a native coarctation).

Aneurysm formation after dilation of recoarctation and native coarctation has been reported by several groups. At present, we routinely dilate recoarctations but tend to send younger patients with native coarctations to surgery unless their surgical risks are increased. In older patients we are increasingly using stents (see later discussion). Other investigators routinely dilate selected native coarctations that are discrete or membranous, reporting minimal residual gradients and a low incidence of complications and aneurysms. Defining the indications in terms of gradient and coarctation diameter is difficult, but our results suggest that conventional balloon dilation is unlikely to be successful in patients with low gradients and a relatively large coarctation luminal diameter.

Branch Pulmonary Artery Stenosis

Branch pulmonary artery stenosis or hypoplasia may be acquired (e.g., at sites of shunts, bands, conduits, or pulmonary emboli) or congenital. Anatomy ranges from single stenotic areas, to multiple stenoses, to diffuse hypoplasia. Successful dilation generally results in tearing of the intima and media (3). Indications for angioplasty include greater than half systemic right ventricular pressure, hypertension in unaffected portions of the vascular bed, marked decrease in flow to an affected portion, and/or symptoms.

Technique
Pulmonary arteries are most commonly dilated from the femoral veins but can be dilated from the subclavian or internal jugular vein or from the femoral arteries in patients with systemic-to-pulmonary artery shunts. Though it is less commonly used, the subclavian or internal jugular approach is easier in many patients. A small pigtail catheter is placed in the femoral artery to monitor pressure, and the patient is heparinized. Right-sided heart hemodynamics are measured, and the magnitude and location of gradients in the pulmonary arteries are determined. In patients with suprasystemic right ventricular pressure or right ventricular failure, creation of an atrial septal defect before dilation may decrease morbidity and mortality. Pulmonary angiograms should include selective injections (anteroposterior and lateral) in each lung and in affected lobes or segments. This is most efficiently accomplished with the use of a side-arm adaptor with a cutoff pigtail over a guidewire. This arrangement allows pressure measurements, angiograms, and dilations to be performed without losing wire position. Angiograms that opacify both lungs are generally not very useful. Lower lobe stenoses in particular are often better seen on the lateral projection, and with the lungs superimposed it may not be possible to visualize stenoses or to differentiate the right from the left lung.

An exchange wire should be positioned in the largest vessel distal to the stenosis to minimize the risk of aneurysm formation, which may occur after overdilatation of small distal vessels. The ideal balloon has a low profile, a short distal tip, and a high maximal inflation pressure. The balloon diameter is chosen to be 2 to 4 times the diameter of the lesion, but not more than 2 times the diameter of the normal vessel on either side (29), (30). The balloon is inflated until the “waist” disappears or until the maximum inflation pressure is reached. If the “waist” does not disappear at low inflation pressures, a pressure gauge is used and balloon rupture should be avoided. Inflation time ranges from 10 to 60 seconds, depending on the response of the “waist” and how well the cardiac output is maintained. After dilation, the balloon catheter is exchanged over the guidewire for a cutoff pigtail catheter and pressure measurements are repeated. Successful dilation may result in a decrease in proximal pressures, a decrease in the gradient, or an increase in the pressure distal to the stenosis. Angiograms are repeated to measure the diameter of the stenosis and to look for tears and aneurysms.

Multiple lesions can be dilated at the same procedure, but care must be taken to avoid previously dilated areas because of the risk of dissection or perforation at the site of a tear. In general, when multiple lesions are present, distal lesions are dilated before proximal lesions and severe stenoses before milder ones.

Results

The criteria for successful dilation have been arbitrarily defined as an increase in diameter of more than 50%, an increase in flow in the affected segment of more than 20%, and/or a decrease of more than 20% in the systolic right ventricular-to-aortic pressure ratio. Using these criteria, the success rate with low-pressure balloons was approximately 60% (36), (37). The use of high-pressure balloons with inflation pressures as high as 21 atm increased the rate to 75% (38). The success rate for postoperative stenoses is higher than for congenital stenoses. The incidence of restenosis is approximately 15%. Complications have included death in approximately 1% of patients secondary to pulmonary artery rupture or pulmonary edema. Dilatation within 4 to 6 weeks after surgery should be avoided because of the risk of vessel rupture. Aneurysms occur in 3% of dilations and are most common in small vessels distal to the stenosis. By positioning the wire in the largest vessel distal to the stenosis and avoiding distal migration of the balloon, the incidence of aneurysms has been decreased. Although the success rate using low-pressure balloons has changed little over the years, the complication rate has decreased due primarily to improved technique. The use of high-pressure balloons does not seem to have significantly altered the complication rate. The success rate has been further increased by the use of intravascular stents (Fig. 28.3) (see later discussion).

FIG. 28.3.

A selective left pulmonary artery injection before (A) and after (B) balloon dilation of the stenotic origin.

COIL EMBOLIZATION OF CONGENITAL AND ACQUIRED THORACIC VESSELS
Therapeutic embolization of unwanted thoracic vessels was first reported in 1974 (39). A number of materials and devices have been used to successfully occlude aortopulmonary collaterals, arteriovenous malformations, Blalock-Taussig shunts, venous collaterals and venae cavae, coronary artery fistulas, and PDAs (40–46). This section discusses the use of Gianturco coils in these lesions.

Coils (Occluding Spring Emboli, Cook, Inc., Bloomington, IN) are stainless steel wires, either 0.018, 0.025, 0.035, 0.038, or 0.052 inches in diameter, embedded with Dacron strands to promote thrombosis. The coil is delivered by positioning a catheter in the vessel to be embolized and then extruding the coil from the catheter by insertion of a guidewire. As the wire coil is extruded from the catheter, it coils to a predetermined diameter (commonly 2 to 12 mm) and shortens significantly compared with the uncoiled length, which varies between 1.2 and 10 cm.

**Technique**

Routine sedation is used, and intravenous heparin (100 units/kg of body weight) is given when vascular access has been obtained. Patients are given an antibiotic (usually cefazolin) before coil embolization and for 24 hours after embolization.

Vascular access for coil embolization depends on which vessels are to be embolized. Most aortopulmonary collaterals, PDAs, and shunts are closed via the femoral or, rarely, the axillary artery. A number of catheters are used to perform angiograms, test occlude vessels, and deliver the coils, and therefore a sheath in the artery is helpful. A major advantage of coils in pediatric patients is that they can be delivered through catheters as small as 3F. Venous collaterals, venae cavae, and pulmonary arteriovenous malformations are closed from the venous side using the femoral, subclavian, or internal jugular vein.

To decide whether to close a particular vessel, one needs to know the hemodynamic consequences of closure and the technical feasibility of embolization. The hemodynamic consequences of closure depend on the vessel to be closed, the presence of other defects, and what surgery the patient has undergone.

Closure of aortopulmonary collaterals, a source of pulmonary blood flow, in patients with cyanotic congenital heart disease results in increased cyanosis if any intracardiac defects remain unrepaired. However, if there are multiple collaterals (or other sources of pulmonary blood flow, such as shunts), closure of some collaterals before complete repair may be possible. This is tested by occluding each collateral with a balloon and measuring the systemic oxygen saturation. If a collateral is the only source of pulmonary blood flow to a segment of lung (i.e., no supply by the native pulmonary arteries), embolization may lead to pulmonary infarction. As with collaterals, test balloon occlusion of surgically created systemic-to-pulmonary artery shunts is required before embolization unless intracardiac defects have been corrected.

Most veins considered for embolization are in patients with Glenn- or Fontan-like procedures. These veins are associated with right-to-left shunts, diminished pulmonary blood flow, and systemic desaturation. Closure eliminates the systemic desaturation but can raise pulmonary artery or right-sided heart pressures. This possibility can be tested by transient balloon occlusion. Similarly, occlusion of a left superior vena cava (SVC) in the absence of an innominate or adequate connecting veins can critically raise pressure above the occlusion, and this should be assessed by test occlusion. Finally, we have seen several patients with atresia of the ostium of the coronary sinus in whom the coronary sinus drains via a persistent left SVC. The presence and anatomy of branches need to be defined. For example, when embolizing a left SVC, one must be careful to position the coils so that the azygos vein does not drain to the left side of the heart.

The most difficult part of most procedures is entering the vessel to be embolized. The availability of a variety of preformed catheters and specialty wires, including tip deflectors and torque-control wires, has made this task easier. Once the vessel has been entered, selective angiograms are used to define the length, the proximal and distal anatomy, the presence of stenoses, and the diameter of the vessel. It is important to realize that the diameter may increase once the vessel is occluded. This is rarely a problem in arteries, but veins are more distensible, and it is therefore best to perform angiograms with the vessels balloon-occluded. Failure to do so can lead to migration of the coils as the vessel enlarges after embolization. Criteria for proceeding with embolization include availability of an appropriately sized coil and a vessel long enough to accept the coil. The presence of distal stenoses decreases the risk of distal
migration. The length and shape of the coil when embolized depend on a number of factors, including the coil-to-
vessel diameter ratio, the distensibility of the vessel, and the diameter of the wire in the coil. If the coil diameter is
too large for a vessel, it will tend to remain straight rather than coil and push the catheter out of the vessel. We
choose the first coil to be about 10% to 40% larger than the vessel diameter.

The type of catheter used to deliver the coil depends on the anatomy of the vessel to be embolized. Attempts are
made to avoid acute angles in the catheter course (which make passage of the coil through the catheter difficult) and
to fix the position of the catheter tip during delivery of the coil with the use of preformed catheter curves. Coils are
extruded from the catheter using the soft end of appropriately sized guidewires. Occasionally, particularly with
tortuous catheter courses, the coil cannot be extruded. If it is still entirely within the catheter, the catheter and coil are
removed. If the coil is partially out the end of the catheter and appropriately positioned, the coil is delivered by rapid
flushing of the catheter lumen with saline using a 1-cc tuberculin syringe.

If the vessel remains patent 5 to 10 minutes after coil placement, additional coils, often smaller than the first, are
placed or blood flow in the vessel is interrupted by balloon occlusion to promote thrombosis. The procedure is
terminated when the vessel is completely occluded or when no space remains for additional coils.

Modified Blalock-Taussig shunts (Gore-Tex tubes), as a group, are technically difficult to coil embolize for several
reasons. Although most native vessels tend to expand or bulge in response to the coil (a property that tends to fix the
coil), rigid Gore-Tex tubes do not. Combined with the high flow and common lack of distal stenoses, this increases
the risk of distal coil migration. Also, coils that are even slightly too large tend to straighten and may push the
catheter out of the shunt. If this happens, the coil may be pulled out of the shunt and embolize to a systemic artery.
For these reasons, we choose coils slightly larger than the shunt and, in some cases, occlude the distal end of the
shunt with a balloon dilatation catheter in the pulmonary artery during coil delivery.

Coronary artery fistulas can be closed either retrograde from the aorta or from the venous side by entering the distal
opening that is commonly into the right atrium. Although standard coronary catheters can be used, the fistulas can be
entered easily with balloon-tip flow-directed catheters owing to their size and high flow. Angiograms should
demonstrate whether there are multiple distal openings, the presence of stenoses, and the location of normal coronary
branches so that one can decide where to position the coils. Test balloon occlusion at that site before coil
embolization is prudent.

Coils have been used to routinely close small PDAs. In contrast to other vessels, coil occlusion of a PDA does not
involve positioning the coil inside the PDA. Rather, the coil is positioned to straddle the PDA, with one or two loops
on the pulmonary artery side and two or three loops on the aortic side. The coil is chosen to be twice the diameter of
the narrowest area of the PDA and long enough to have 4 loops when coiled. The coils can be delivered via venous
or arterial access. Using a retrograde approach from the femoral artery, the catheter is advanced through the PDA
into the pulmonary artery. Approximately one third (1 to 1.5 loops) of the coil is advanced out the catheter, and the
catheter is pulled back until the loops are at the pulmonary end of the duct. The catheter is then withdrawn over the
coil and guidewire, and the rest of the coil is delivered on the aortic side of the PDA. Multiple coils can be delivered
simultaneously or sequentially with minimal risk of migration.

Results

Coil embolization is a very common intervention in our catheterization laboratory, and hundreds of vessels have been
embolized (Fig. 28.4). Many embolizations eliminate the need for surgery, but more commonly, as with
aortopulmonary collaterals or left SVC, they simplify surgery and allow the surgeon to concentrate on the
intracardiac anatomy. The success rate for coil embolization is very high. With torque-control wires and a variety of
preformed catheters and tracker systems, almost any vessel can be cannulated and coil-embolized. Of those
embolized, more than 90% are completely occluded, and the recanalization rate is less than 5%. The most common
complication, occurring in fewer than 1% of cases, remains migration of the coil out of the vessel being embolized.
The coil can almost always be retrieved with the use of a snare or basket.

FIG. 28.4.
An aortopulmonary collateral from the descending aorta to the right lung before (A) and after (B) coil embolization.

The results of coil embolizations of PDAs are excellent. Approximately 95% of PDAs smaller than 2.5 to 3 mm can be completely occluded with a single coil. Larger PDAs can also be coil-occluded, but they commonly require multiple coils. The technique has several advantages over other devices, including technical ease, smaller delivery catheters, and decreased cost. Most PDA devices are now designed for large PDAs.

DEVICE CLOSURE OF ATRIAL OR VENTRICULAR SEPTAL DEFECTS, AND PATENT DUCTUS ARTERIOSUS

Transcatheter closure of a PDA was first reported by Porstmann et al., in 1971 (47) using a plug that is still used successfully in some centers (48). King and Mills (49) reported the first transcatheter closure of ASDs by a double-disk device in 1976. In the 1980s, Rashkind developed a single umbrella (50) to close ASDs, but its use was associated with multiple problems and few successes. He later developed a double umbrella (51) to close PDAs and it was used successfully in large numbers of patients. Lock et al., first used this double umbrella to close selected ASDs and VSDs and later developed the Bard Clamshell Device (52–58), which was the first device to be used in large numbers of patients to close ASD secundum, patent foramen ovale (PFO), and VSDs. It was also used in a variety of other defects, including coronary artery fistulas, left ventricular apex-to-descending aorta conduits, SVC-to-right atrial communications occurring after Glenn shunts, SVC andazygos veins, Potts anastomoses, large aortopulmonary collaterals, large arteriovenous malformations, and paravalvar leaks. The last several years have witnessed an explosion in the device field. The double umbrella has continued to undergo modifications, and new devices have been appearing with increasing frequency. Most of the new devices were developed initially for ASD closure, but some have been modified to allow closure of PDAs and VSDs. The current list of ASD devices includes the CardioSEAL (a modified clamshell) (Nitinol Medical, Boston, MA) and its modification, the STARFlex; the button device (Custom Medical Devices, Amarillo, TX); the ASDOS device (Osypka Corporation, Germany); the Das-Angel Wings device (Microvena, Vadnais, MN); and the Amplatzer Septal Occluder (AGA Medical Corporation, Golden Valley, MN) (59–68). Many of these devices are used routinely outside the United States, but currently none has been approved by the U.S. Food and Drug Administration. Of the current devices, the double umbrella (CardioSEAL and STARFlex) and the Amplatzer appear to be the most promising; they are discussed in the following sections.

Closure of Atrial Septal Defects

Technique

Although the techniques for loading, positioning, and releasing the various devices differ, the overall approach for transcatheter closure of ASDs is similar for most devices (Fig. 28.5). The devices are designed to close a secundum ASD or PFO, but primum and sinus venosus ASDs are not closed because of their proximity to the atroventricular valves and pulmonary veins, respectively. Devices are positioned by a combination of fluoroscopy and transesophageal echocardiography. The latter technique is especially useful for secundum ASD (69), but it is generally not needed for small PFOs. In most cases, general anesthesia is used and the patient is heparinized and receives prophylactic antibiotics. Access for closure is almost always via the femoral vein, although a few devices have been implanted via the internal jugular or the hepatic vein. After routine hemodynamic measurements, the defect is sized in two ways. First, it is measured echocardiographically, and then the stretched diameter is measured by pulling a sizing balloon across the defect or using a static balloon. In general, the stretched diameter is 20% to 30% larger than the unstretched diameter. The choice of device size is usually based on the stretched diameter.

FIG. 28.1.

A right atrial injection (A) with levophase (B) demonstrating complete closure of a secundum atrial septal defect with a 27-mm clamshell umbrella.
The CardioSEAL consists of two square Dacron umbrellas, each supported by four spring-loaded arms constructed of MP35N. It is available in 17-, 23-, 28-, 33-, and 40-mm sizes, the size corresponding to the diagonal of the square. The delivery system normally requires an 11F sheath. The STARFlex is a modification in which flexible nitinol springs run back and forth between the arm tips of the two umbrellas, a system that promotes self-centering. In addition, the delivery system has been modified to allow use of a 10F long sheath for delivery and more flexibility of the device before release. In general, the CardioSEAL is chosen to be twice the diameter of the stretched diameter of the ASD. With the self-centering mechanism, a smaller STARFlex device, 1.6 to 1.8 times the diameter of the defect, can be used. After balloon-sizing, a long sheath is advanced over a guidewire from the femoral vein to the left atrium, and the dilator and guidewire are removed. One must be very careful to avoid emboli through the long sheath. The double umbrella is loaded into the delivery system by collapsing the left atrial umbrella distally and the right atrial umbrella proximally. The delivery system is then advanced to the end of the long sheath. Retraction of the long sheath allows the left atrial umbrella to open. The entire system is then withdrawn under echocardiographic guidance until the left atrial umbrella is near the septum. The sheath is then withdrawn to allow the right atrial umbrella to open. If all of the arms are correctly positioned by echocardiography, the device is released. The device can be pulled back into the sheath if only the left atrial umbrella has been opened. Retrieval is more difficult if both umbrellas have been opened, but it can almost always be retrieved with the use of transcatheter techniques.

The Amplatzer Septal Occluder is constructed of 0.004- to 0.005-inch nitinol wires that are tightly woven into a right and left atrial button connected by a 4-mm waist. The device size is determined by the waist and, currently, multiple sizes between 4 and 34 mm are available. The device is filled with polyester threads to enhance thrombogenicity. The device is loaded by stretching, which eliminates the discs and waist. The smaller sizes can be delivered through a 7F long sheath. The device is designed to stent the defect open and the device size is chosen so that the waist is equal to the stretched diameter. Delivery is similar to the double umbrella in that the left atrial disc is opened first, followed by the right atrial disc. One advantage of the Amplatzer is that the device can be pulled back into the sheath even if both discs have been opened.

**Results**

There is a rapidly growing literature regarding the results of device closure of ASDs (70–79). Because it has been available in one modification or another, the double umbrella device has the largest and longest follow-up. With the original clamshell device, successful implantation was accomplished in 94% of cases, with an incidence of severe complications of 6% (death, cerebral vascular accident, need for emergent operation, tamponade, cardiac arrest, or severe dysrhythmia). The complication rate decreased in later studies with the use of the CardioSEAL. In follow-up reviews of more than 500 patients, the incidence of late transient ischemic attacks and arrhythmias was less than 1% and endocarditis was not seen. Residual leaks occurred in 39% but were significant in only 6%. Preliminary results with the STARFlex modification suggest that it has significantly higher closure rates than the CardioSEAL.

The Amplatzer device was successfully implanted in 100% of patients and achieved complete closure in 95% at 3 months. The incidence of severe complications at the time of implantation was 1.7%. Complications early in follow-up were uncommon but included both transient ischemic attacks and endocarditis. Long-term follow-up results are not yet available.

Although the procedure is not yet approved in the United States, many centers elsewhere routinely close secundum ASDs. With ongoing modifications to existing instruments and the advent of new ones, it should not be long before such devices are approved in this country. In addition to clinical trials for secundum ASDs, trials are also underway to determine the efficacy of devices for closing fenestrated Fontans and for closing PFOs in stroke patients.

**Closure of Ventricular Septal Defects**

Transcatheter closure of VSDs was first reported by Lock et al., in 1988 (53). They used the Rashkind PDA double umbrella to close small defects. The development of the clamshell device allowed closure of larger defects (80), and the CardioSEAL and STARFlex modifications of the clamshell are now used for VSD closure (Fig. 28.6). The Amplatzer device has been modified to allow closure of VSDs (81). Currently available devices do not lend themselves to closure of the most common type of VSD, the perimembranous defect, owing to the proximity to the aortic valve. Rather, device closure is used for muscular defects, congenital or postinfarction, and for patch margin defects. These are the defects with which surgeons have the most difficulty.
Technique

FIG. 28.6.

A: Left ventriculogram demonstrating a midmuscular ventricular septal defect (VSD). B: Selective injection in the VSD with a pigtail over a wire from the femoral vein through the atrial septum and VSD and out the superior vena cava and internal jugular vein. C: Left ventriculogram taken after umbrella placement demonstrates complete closure. The contrast material in the right ventricle is from a malalignment VSD, which was closed surgically.

Precatheterization Doppler echocardiograms should define the number, location, and size of the VSDs and the relationship of these defects to the atrioventricular and semilunar valves.

A VSD is usually easier to cross from the left to the right ventricle, rather than vice versa, because of the smooth left ventricular surface and the left-to-right shunt present in most defects. The left ventricle can be entered retrograde from the aorta or transseptally from the venous side and across the mitral valve. The choice depends on patient size and VSD location. Right- and left-sided hemodynamics are measured, and a left ventriculogram is performed in a projection most likely to profile the VSD. The decision must then be made as to what venous access to use for device delivery. A middle or apical muscular VSD is easiest to close via the internal jugular vein or via the transseptal approach from the femoral vein, because the course is straighter and the sheath is less likely to kink. On the other hand, an anterior muscular VSD is easiest to close from the right ventricular side via the femoral vein. The VSD is crossed from left to right. An exchange wire is then advanced out of that catheter, snared, and drawn out through the skin at the venous site to be used for closure. It is important to avoid getting the wire entangled in the tricuspid valve apparatus. This wire now runs from either the femoral vein or artery through the heart, across the VSD and out (e.g., internal jugular vein). Traction on this wire can damage the heart or induce aortic or mitral regurgitation depending on its course. This wire is used to take selective pictures in the VSD using a pigtail catheter and Y-arm adaptor and for balloon sizing of the defect, although balloon-sizing is not as important for VSDs as for ASDs. Gentle traction on the through-and-through guidewire facilitates positioning of the long sheath across the defect.

For double umbrellas, the device is chosen to be 1.6 to 2 times the diameter of the defect. For the Amplatzer device, the waist of the device is chosen to equal the diameter of the defect. Device delivery is similar to that described for ASDs.

Results

Between February 1989 and July 1998, 148 VSDs were closed at Boston Children's Hospital with no deaths or late morbidity resulting from the procedure. Echocardiographic follow-up studies showed that 83% of the defects either were closed or had trivial residual leaks. Because of the presence of multiple defects, many patients had multiple devices placed. As a result the complexity and extent of the catheter manipulation involved, transient arrhythmias and hemodynamic compromise were not uncommon during these procedures (82). Other complications included asymptomatic hemothorax and a case in which the umbrella compromised the septal leaflet of the tricuspid valve. There is very limited experience with the recently released Amplatzer VSD device.

Patent Ductus Arteriosus Occlusion

As noted previously, coils are now used to close the most common small PDAs. PDAs larger than 3 mm usually require multiple coils. While this may be a reasonable option in many patients, there are other devices that can be used for larger PDAs. Currently, the only approved device is the Grifka bag (Cook) (83). This device is similar in concept to a detachable balloon, but instead of being fluid filled it is a nylon bag filled with a coil. It requires an 8F sheath and is usually delivered from the venous side, as are most devices. The fact that secure positioning requires a PDA with some length has limited its use. The Amplatzer device comes in a PDA design and is in clinical trials in this country. The clamshell has been used successfully to close large PDAs, and the CardioSEAL has been used occasionally to close large PDAs in patients who are at increased surgical risk as part of a high-risk protocol.
INTRAVASCULAR STENTS

Since 1989, when intravascular stents were first implanted in a patient with branch pulmonary artery stenosis, they have become an integral part of the management of congenital heart disease (84–87) (Fig. 28.7). In the last 10 years, 477 patients have undergone stent implantation at Children's Hospital, Boston. The most common lesions were branch pulmonary arteries in 246 patients, obstructed right ventricular-to-pulmonary artery conduits or homografts in 108 patients, and coarctation of aorta in 32 patients. Other sites included obstructed Fontan baffles or conduits in 21 patients, stenotic pulmonary veins in 18 patients, systemic ventricular outflow tract obstructions in 14 patients, stenotic aortopulmonary collaterals in 12 patients, and systemic venous obstructions in 16 patients. Uncommon, although often successful, uses of stents have included peripheral arterial obstructions, the creation and maintenance of ventricular and atrial septal defects and Fontan fenestrations, stenotic or thrombosed Blalock-Taussig shunts, and in patent ductus arteriosus to maintain patency in duct-dependent lesions.

FIG. 28.1.

A: Left ventriculogram in a patient with 'S,L,L' a single left ventricle demonstrates a restrictive bulboventricular foramen (BVF). B: A spot cine film of an 18-mm iliac stent expanded to 12 mm in the BVF. C: Repeat ventriculogram taken after stent implantation. The peak systolic ejection gradient was reduced from 70 to 10 mm Hg.

Technique

We have used balloon-expandable Palmaz stents from Johnson and Johnson. The most commonly used sizes are the 10-, 15-, and 20-mm-long biliary stents (predilation diameter, 2.5 mm) and the 12-, 18-, and 30-mm-long iliac stents (predilation diameter, 3.4 mm). The biliary stents can be expanded to approximately 12 mm in diameter and the iliac stents to 18 mm. Because of their design, the Palmaz stents shorten as they expand.

Balloons available for stent implantation continue to improve. In the past, the most common technical problems with stent implantation were the stent slipping off the balloon during positioning and expansion and balloon rupture during inflation. These problems have been largely overcome with the advent of balloons with surfaces that resist slippage and are scratch resistant. The unique balloon-in-a-balloon (NuMed) has further reduced the technical difficulties of stent implantation.

Stents can be implanted in most patients with the use of routine sedation. General anesthesia is reserved for patients who cannot be controlled with sedation and in those who are likely to be hemodynamically unstable during implantation. Once percutaneous access has been obtained, heparin (100 units/kg body weight) is given, and the activated clotting time is maintained at more than 200 seconds. Prophylactic cefazolin is given before implantation and for 24 hours after implantation.

In most patients, a balloon is inflated in the lesion before stent implantation. This allows determination of the balloon expandability of the lesion and the use of high-pressure balloons, if necessary, before stent implantation. Because it is rarely possible to reposition an expanded Palmaz stent, it is important to position the stent and balloon properly during inflation. Inflating a balloon before stent implantation allows one to determine the optimal balloon position, diameter, and length and to change the guidewire if necessary.

The stent is mounted and crimped onto the appropriate balloon. A long sheath is used to protect the stent as it is advanced to the lesion. One of two techniques can be used. First, the long sheath is positioned across the lesion, and the balloon is advanced over a guidewire through the sheath. The second option is to advance the balloon through the long sheath outside the body. The stent is then mounted on the balloon and retracted into the sheath, leaving the distal tip of the balloon exposed to act as a dilator. The system is then advanced as a unit over the guidewire. The latter technique has two advantages. It eliminates the problem of advancing the stent past kinks that can develop in the sheath with the first technique. It also allows the use of smaller sheaths. The size of the sheath used depends on the balloon and stent size but is most commonly 7F or 8F for biliary stents and 8F to 12F for the iliac stents. An extra-stiff exchange-length guidewire with a short, floppy tip facilitates positioning of the stent and stabilizes the balloon.
during inflation. With either technique, a side-arm adaptor at the proximal end of the sheath prevents blood loss and allows injections of contrast material to ensure proper positioning of the stent before inflation. When the stent is in position, the long sheath is retracted and the balloon is inflated. Angiograms and hemodynamic measurements are repeated after implantation.

Anticoagulation during the catheterization is achieved with heparin. Patients who have pulsatile flow through the stent are given heparin for at least 12 hours and aspirin for at least 6 months. For stents with nonpulsatile flow, patients are given warfarin for 6 months and heparin until the prothrombin time is elevated.

**Results**

The most common indication for stent implantation remains branch pulmonary artery stenosis (88). The majority have been implanted in the proximal left or right pulmonary artery. Implantation more distally in the lung is limited by the multiple branches, so that stenting of one branch opens others; such covered branches, however, are not necessarily occluded by the stent. In the first 77 patients at our institution, the diameter of the stenosis was increased from an average of 3.8 to 8.3 mm, or an average of 120%. The gradient was reduced from 53 to 20 mm Hg, and the right ventricular pressure as a percentage of systemic pressure was reduced from 88% to 62%. These are significantly better results than those achieved with conventional dilation. Follow-up analyses have demonstrated a very low incidence of restenosis.

The second most commonly stented lesion has been right ventricular-to-pulmonary artery homografts and conduits (89). In our first 50 patients, the diameter of the narrowest area was almost doubled and the gradient was reduced by approximately 50%. Stenting has prolonged the life of homografts, on average, by 2.5 years. Stents have proved very useful in systemic venous obstructions, including baffle obstructions occurring after Mustard or Senning repairs of D-transposition of the great arteries. We have implanted stents inside the heart in seven patients with left ventricular outflow obstruction. The sites of obstruction have included restrictive VSDs in patients who have undergone a Rastelli-type repair, tunnel subaortic stenosis, and an obstructed left ventricular-to-descending aorta conduit.

The fastest growing indication for stents in patients with congenital heart disease over the last few years has been coarctation (90). Initially, stents were implanted primarily in patients with recoarctations who were at increased surgical risk and for whom conventional dilation had failed. Their success in that group led to their evaluation for other indications. These include the use of primary stenting for native and postoperative coarctations in adults. This approach, which avoids conventional dilation, reduces the size of the balloons used and may decrease the incidence of aneurysms, dissections, and rupture. Another group comprises those with relative mild stenoses and gradients less than 20 mm Hg who may nonetheless develop left ventricular dysfunction, systolic and/or diastolic. Neither conventional surgery nor balloon dilation has much to offer this group, but stents can reduce or eliminate the gradient in most patients. The ultimate indications in patients with coarctations await further study.

Significant nontransient complications during implantation are rare. The most common remains stent malposition, which occurs in approximately 1% of cases. The most common reason is balloon rupture during inflation. Although most malpositioned stents can be left, occasionally a patient is sent to the operating room for removal. Stent fracture during follow-up has been seen, and the incidence varies with the lesion stented. We have not seen it in pulmonary artery stents, but approximately 10% of homograft stents fracture. The only complication of fracture has been recurrence of the gradient.

At present, neither the indications nor the contraindications to stent implantation are absolute, and the continue to change as experience is gained. For example, stent implantation in small infants should be avoided because the stents do not grow and the ability to redilate stents is somewhat limited. However, we have now implanted stents in many infants who, at the time, had no good medical or surgical options. The stents were implanted in locations accessible to the surgeon (e.g., not in the distal pulmonary arteries), and many of the patients have subsequently gone to surgery, where stent removal has not been a problem. The indications also will change with the availability of new stent designs, including covered stents (91), biodegradable stents, and stents that allow dilation of side branches that have been covered by stents.