Conferences and Reviews

Therapeutic Cardiac Catheterization in Children

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Cardiac catheterization, once the mainstay of diagnosis in children with congenital heart disease, has become a therapeutic modality for many conditions. Balloon dilatation can now open stenotic valves and vessels, coils and umbrellas can now close unwanted communications, and emboli can be withdrawn without surgical intervention.

(Waldman JD, Swensson RE: Therapeutic cardiac catheterization in children. West J Med 1990 Sep; 153:288-295)

From the introduction of a catheter into the human vascular system in 1929[1] through the work of Andre Cournand (for which he was awarded the Nobel prize in 1956) to the present, cardiac catheterization has been used as a diagnostic tool. In the late 1960s, pediatric cardiologist William Rashkind, MD, first used catheterization as a therapeutic modality,[2] and recent advances have expanded the use of this technique. In this report, we summarize the current status of therapeutic cardiac catheterization in children, with specific reference to the experience at the San Diego Regional Pediatric Cardiac Program (Table 1).

Creating an Atrial Septal Defect

Initially done to create a low-pressure site for intercirculatory mixing in patients with transposition of the great arteries, balloon atrial septostomy is now also used when there is stenosis or atresia of an atrioventricular valve in order to decompress the obstructed side of the heart. The technique described by Rashkind and Miller in 1968 has been only minimally changed over the years,[3] but modern ultrasound technology can noninvasively assess the location and size of the tear in the septum primum[4] as well as quantify the interatrial flow.

From 1978 to 1989, balloon atrial septostomy has been carried out in 147 neonates and infants. Most (84%) had transposition of the great arteries. In four the procedure was unsuccessful: three had a hypoplastic left-heart syndrome and the left atrium was too small to accept an inflated balloon, and one newborn with transposition of the great arteries and bilateral left-sided atrial appendages died of a tear in the base of the anomalously originating right atrial appendage. Two patients had complete heart block resulting from the procedure. Excellent palliation was achieved in 96%, and this high success rate can be related partly to the use of large volumes (average, 4 ml) in the balloon and partly to the performance of the procedure by experienced attending physicians.

A newer technique for creating an atrial septal defect was developed by Park and colleagues in 1978.[5] By using an extendable and retractable blade at the catheter tip, the atrial septum is incised rather than torn. This procedure is useful in those with a thick atrial wall, especially older children. After a blade septotomy, a balloon septostomy technique is used to enlarge the defect. We have used this combination approach in six patients: four with pulmonary atresia and an intact ventricular septum and two with transposition of the great arteries. No problems were encountered, and each child received adequate palliation.

Closing an Atrial Septal Defect

Just as in some patients an interatrial communication is needed, in others—that is, patients with naturally occurring defects in the atrial septum—the communication may be closed nonoperatively. This has been tried using various devices,[6,7] the most recent being a biconvex ("double clamshell") apparatus that shows promise in initial trials. Results must be judged, however, in comparison to a surgical procedure that has essentially no morbidity or mortality. Transcatheter closure of atrial septal defects remains at present an experimental procedure with which we have had no experience.

Balloon Dilatation

The technique for balloon dilatation is similar in most lesions, the major difference being the calculation of the appropriate (safe but effective) balloon size. After baseline hemodynamic studies and angiography, an end-hole-tipped catheter is manipulated across the obstruction and a long (exchange) wire is fed through the catheter into the distal vessel or chamber. The catheter is then removed, leaving the wire in place, and the balloon dilatation catheter is advanced over the wire until the balloon is centered over the stenosis. The balloon is then inflated rapidly several times to a very high pressure in the hope of tearing the obstruction (valve or vessel) without causing rupture. Hemodynamic studies and angiography are repeated, with the contrast dye being injected well away from the dilated (and therefore weakened) area.

Native Pulmonary Valve Stenosis

Balloon dilatation is now recognized as the procedure of choice in correcting stenosis of a native (as opposed to a prosthetic) pulmonary valve.[8] The technique and results have been well described.[9,10] Using balloons 40% to 50% larger than the pulmonary anulus,[11] it is possible to nearly obliterate the gradient (Figure 1) by tearing the fused valve tissue along the incomplete raphe.[12]

In our program, 51 children have had balloon dilatation

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of native pulmonary valve stenosis. No problems were encountered with any procedure. Each had a systemic or suprasystemic pressure in the right ventricle with gradients of 40 to 105 mm of mercury. Echocardiography interfaced with Doppler flow analysis proved extremely accurate in identifying the need for balloon dilatation and in measuring the anulus for the choice of balloon size. A reduction in both the gradient (Figure 2) and the right-left ventricular pressure ratio was noted in all cases; 31 (61%) had gradients after dilatation of less than 20 mm of mercury, and 11 of the 51 (22%) had gradients of less than 10 mm of mercury after the "pulmonary valvotomy without thoracotomy." Some patients were seen to have muscular subpulmonary narrowing on the echocardiogram taken immediately after the procedure; this dynamic obstruction generally resolved with time and may account for the transient residual gradients.

Reported short-term follow-up indicates that the low gradient after balloon dilatation either persists or can even regress further spontaneously[13]; our experience supports this observation. Long-term follow-up—over decades—is unavailable, but it seems likely that balloon dilatation will remain the procedure of choice for correcting stenosis of the pulmonary valve.

TABLE 1.—*Experience With Therapeutic Cardiac Catheterization (TCC) at the San Diego Regional Pediatric Cardiac Program, 1978-1989*

Types of TCC	*Procedures, No.*
Creation of atrial septal defect	
Balloon septostomy	147
Blade septotomy	6
Balloon dilatation of	
Native pulmonary valve	51
Native aortic valve	22
Recoarctation of the aorta	24
Porcine "pulmonary" valve	10
Branch pulmonary arteries	13
Mitral valve, rheumatic	2
Obstruction to superior vena cava	1
Discrete subaortic stenosis	2
Pulmonary vein stenosis	0
Closure therapy	
Atrial septal defect	0
Patent ductus arteriosus	6
Arteriovenous malformations, collaterals	6
Retrieval of intravascular embolus	5

Coarctation of the Aorta

After initial successes with balloon dilatation in unoperated children with coarctation,[14-17] concern was raised about the incidence of aortic aneurysms at the site of balloon dilatation.[18-21] At this time, the controversy is still unresolved as to the appropriateness of the procedure in these children, especially as the risk of balloon dilatation may be higher than of an operation. By contrast, there is general unanimity that balloon dilatation is the preferred approach to residual or recurrent coarctation for two reasons[22,23]: scarification in the operative area makes disruption or aneurysm of the aorta unlikely, and reoperation on the same site carries a higher risk of morbidity and a lesser chance of success.

Balloon dilatation of recurrent coarctation has been done in 24 patients in our program. Of these, 23 were successful (Figure 3). The single failure occurred in a 28-year-old man, 24 years after surgical repair. Despite the use of two large balloons, the lateral pressure delivered may have been inadequate to achieve a therapeutic tear in the stenotic vessel wall.

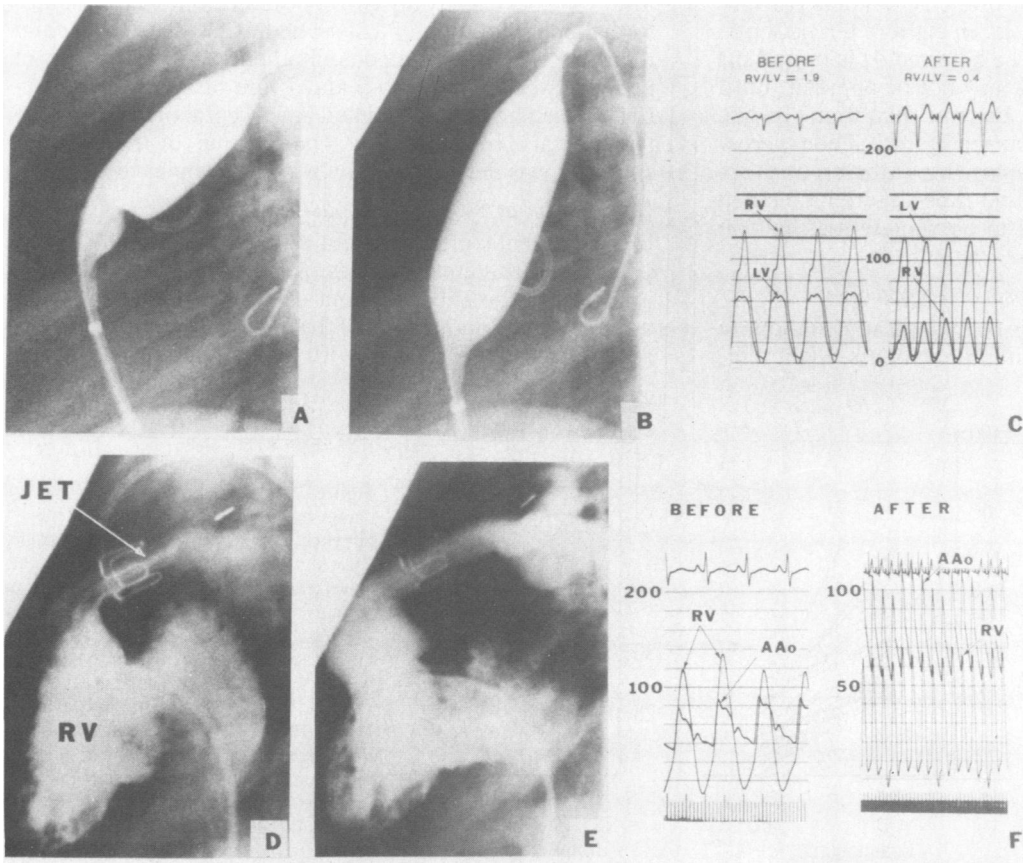

Figure 1.—Balloon dilatation (BD) is used to correct pulmonary valve stenosis, native or artificial. In a patient having BD of stenosis of a native pulmonary valve, **A,** the balloon, indented by the stenotic native pulmonary valve, is not in the proper position for BD as the midpoint of the balloon should be at the location of maximum obstruction. **B,** Having been pulled to a more proximal position, the balloon is inflated under high pressure, obliterating the "waist" or narrowing caused by the stenotic valve. **C,** The pressure change effected by BD converts the right ventricular (RV)-left ventricular (LV) pressure ratio from 1.9 to 0.4, decreasing the RV systolic pressure from 130 to 45 mm of mercury. In a patient with a stenotic RV-pulmonary artery porcine-valve conduit, RV angiogram **D** shows a "jet" through a stenotic porcine valve in the pulmonary position. **E,** After BD of the porcine valve, a large bolus passes through the valve. The conduit shows no evidence of pseudointimal proliferation. **F,** Before BD, the RV pressure is 120 with an ascending aortic (AAo) pressure of 85 to 90 mm of mercury. After BD, with the scale changed to 0 to 100, the RV-AAo pressure ratio is 0.6 with a systolic RV pressure of 65 mm of mercury, essentially half the pre-BD value. The angiograms **(A, B, D, E)** are all lateral views.

Native Aortic Valve Stenosis

In theory, balloon dilatation to correct aortic valve stenosis is an excellent alternative to surgical aortic valvotomy because it is precise and avoids the use of a median sternotomy.[24-26] But it is often done on the sickest infants, is technically demanding, is traumatic on the femoral vessel(s), may result in considerable blood loss, and carries a reported complication rate of 40%,[27] the highest of all balloon dilatation procedures. Thus, while balloon dilatation may be considered a reasonable alternative to surgical intervention in isolated cases of valvar aortic stenosis, it should be approached with considerable caution, and the parents must be well informed of all the risks involved.

In our center 22 children have had balloon dilatation for aortic stenosis, including a 2.5-kg neonate with severe low cardiac output and two infants aged 3 and 4 months (Figure 4). The average gradient was reduced from 64 to 30 mm of mercury. One child died of a probable ventricular dysrhythmia six hours after a balloon dilatation that was confirmed to be anatomically successful at autopsy. No child had significant aortic regurgitation (Figure 5) after balloon dilatation, but 5 of 21 (24%) survivors had complications—cardiac arrest, blood loss requiring transfusion, permanent loss of femoral pulse—supporting the contention by Fellows and colleagues that balloon dilatation for aortic stenosis has the highest morbidity rate of all such procedures.[27] It is too early to assess the moderate-term effect in these children, but 17 of the 21 survivors have not required an operation during a follow-up of as long as 28 months.

Stenosis of a Bioprosthetic 'Pulmonary' Valve

We have used balloon dilatation for stenotic porcine valves[28] within right ventricle-pulmonary artery conduits in ten children. Although a substantial reduction in the right ventricular pressure was usually achieved, angiography after balloon dilatation of the valve often showed additional obstruction at a conduit-branch pulmonary artery anastomosis; this was also dilated. In eight of ten patients, the conduit replacement could be deferred. It is important to seek out distal stenoses that may not be apparent until after the valve has undergone balloon dilatation. In one child, a circumferential tear occurred in the balloon, necessitating a femoral cutdown to remove the catheter; no problems were encountered in the other nine children. Calcified conduit valves may predispose to circumferential balloon tears or an embolus of a balloon fragment.[29]

Branch Pulmonary Artery Stenosis or Hypoplasia

Balloon dilatation of stenotic or hypoplastic pulmonary arteries[30,31] was done 13 times in nine patients. Eight children had postoperative obstruction following the correction of cyanotic congenital heart disease; adequate relief was accomplished in five.

One child with congenital hypoplasia of the pulmonary arteries had two successful balloon dilatations (Figure 6) but sustained a rupture of the left pulmonary artery at the third one; he required emergency surgical repair from which he recovered well. Congenital pulmonary artery hypoplasia is fundamentally different from postoperative obstruction. The therapeutic effect of balloon dilatation is accomplished by creating a transmural arterial tear through the intima and into the media (see Figure 6-C)[32]; vascular integrity is preserved by the adventitia. When a patient has had an operation, the area surrounding the obstruction has been dissected and manipulated, with resulting scar tissue. In contrast, a congenitally hypoplastic artery has no surrounding scarification and the walls may be thin between the bands of obstruction. Thus, balloon dilatation of postoperative branch pulmonary artery stenosis appears to have a relatively low risk, but the same procedure of congenitally hypoplastic pulmonary arteries may pose a higher risk.

A recent preliminary report provides some encouragement for patients with congenital peripheral pulmonary artery stenosis because of the successful insertion of internal stents to maintain the expanded internal dimension and avoid restenosis.[33] It is hoped that this technique will soon be available for expanded clinical trials.

Rheumatic Mitral Valve Stenosis

While successful balloon dilatation of congenital mitral valve obstruction has not been reported, good results have been obtained in patients with rheumatic mitral valve stenosis.[34-36] Technically, this requires inserting a long sheath across the atrial septum for placing the balloon dilatation system and often the use of two balloons simultaneously. Because rheumatic carditis is rare in southern California, we have seen only two children who were candidates for balloon dilatation of a stenotic mitral valve. Each child required two 20-mm balloons. Gradients of 19 and 21 mm of mercury were reduced to 5 and 7 mm of mercury, respectively. Each had a tiny residual atrial septal defect from the transseptal procedure, but the volume of left-to-right shunting was detectable only by color Doppler technology.

Obstruction to Systemic Venous Return

Occasionally after a venous switch operation for transposition of the great arteries, there is obstruction at the junction of the superior vena cava and right pulmonary artery or in the midportion of the new "right atrium." While success has been reported with balloon dilatation,[37,38] our

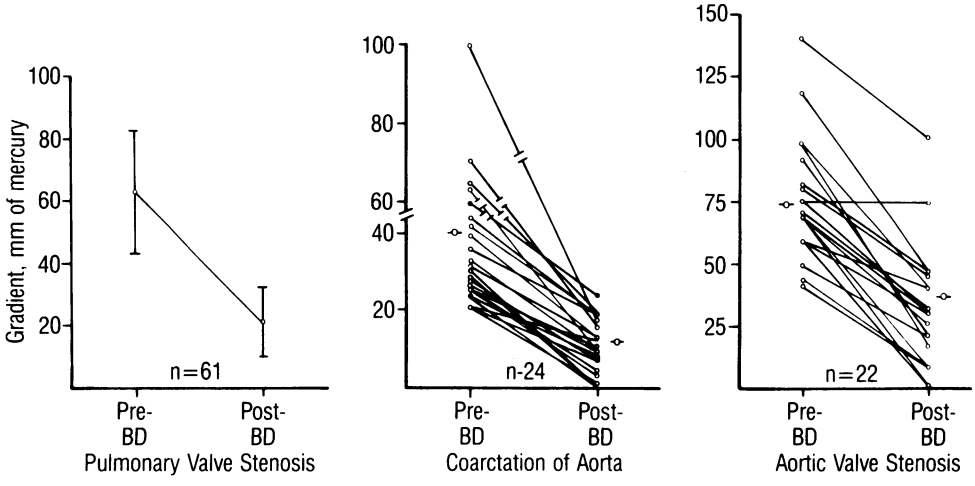

Figure 2.—Acute pressure changes are caused by balloon dilatation (BD). **Left,** In 61 patients (51 with BD of a native pulmonary valve and 10 with stenosis of a bioprosthetic valve), the average gradient was 64 mm of mercury before BD and 22 mm of mercury after BD. **Middle,** In 23 of 24 patients, the gradient across a recurrent aortic coarctation was reduced. Gradient reduction was more dramatic in those with greater pressure differences pre-BD. **Right,** In those with aortic valve stenosis, variable degrees of gradient reduction are noted. Several with minimal response to BD had more than 1 level of left ventricular outlet obstruction. -o- = mean values

experience showed that an initial good result may not persist over time.[39] Long-term follow-up is needed to determine whether this mode of treatment is truly useful.

Discrete Subaortic Stenosis

Reports from Spain and Columbia, Missouri, describe the successful use of the balloon dilatation technique for discrete subaortic stenosis in 17 children.[40,41] In our program, two patients have had balloon dilatation for subaortic stenosis, each for esoteric reasons: one was an illegal alien for whom funding was unavailable and the second had propionic acidemia, a metabolic disorder wherein the risk of an operation was considered prohibitively high. In both patients, echocardiography showed a substantial reduction in the anatomic obstruction; in the first child, other levels of left ventricular outlet obstruction made the gradient reduction small, and in the second child, the gradient was reduced by balloon dilatation to zero from 60 mm of mercury. Surgical repair continues to be the preferred option for subaortic stenosis but, in rare instances, balloon dilatation may be an acceptable alternative.

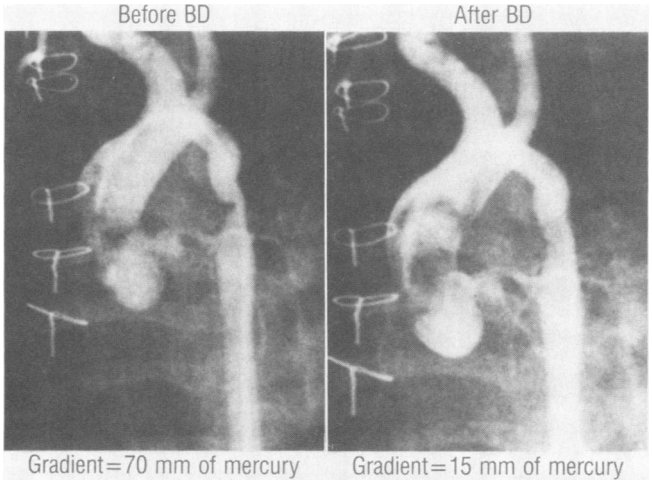

Figure 3.—Lateral angiograms taken of a patient having balloon dilatation (BD) for recurrent coarctation of the aorta show, **Left,** before the procedure, both discrete and long segment narrowing with a gradient of 70 mm of mercury from the right arm to legs. This patient had had a subclavian flap aortoplasty repair of coarctation at another center. Note the absence of the subclavian artery. **Right,** After BD, the aortic constriction is abolished and the gradient was reduced to 15 mm of mercury. (A dramatic clinical improvement occurred.)

Pulmonary Vein Stenosis

Pulmonary vein stenosis is a condition not surgically correctable, and, therefore, it was with considerable hope that balloon dilatation was applied to five children in Texas and six in Boston with this uniformly fatal lesion.[42,43] Although the results were initially successful, stenosis recurred in each case. Thus, no lasting benefit was provided by currently available balloon dilatation techniques. We have not attempted the procedure in any patient with pulmonary vein stenosis. As with pulmonary artery hypoplasia, internal stents may be useful in this condition.

Closure of Patent Ductus Arteriosus

Per catheter closure of persistent patent ductus arteriosus has been performed with various devices, including double balloons,[44] preformed plugs,[45] a plug plus an umbrella,[6] and a double-umbrella device—the Rashkind occluder[46]—that has recently been approved for clinical use by the US Food and Drug Administration. A combined report from Philadelphia, Pennsylvania, Houston, Texas, and New Haven, Connecticut, showed a success rate (complete closure) of 78% with an embolization incidence of 10%.[47] Even more recent data indicate a success rate in the 90% range with further modifications in technique (J. E. Lock, MD, oral communication, November 1989). Our experience in San Diego is limited. We have used the Rashkind occluder six times with good results (Figure 7) in four patients and embolization in two (one anticipated because of pulmonary vascular obstructive disease).

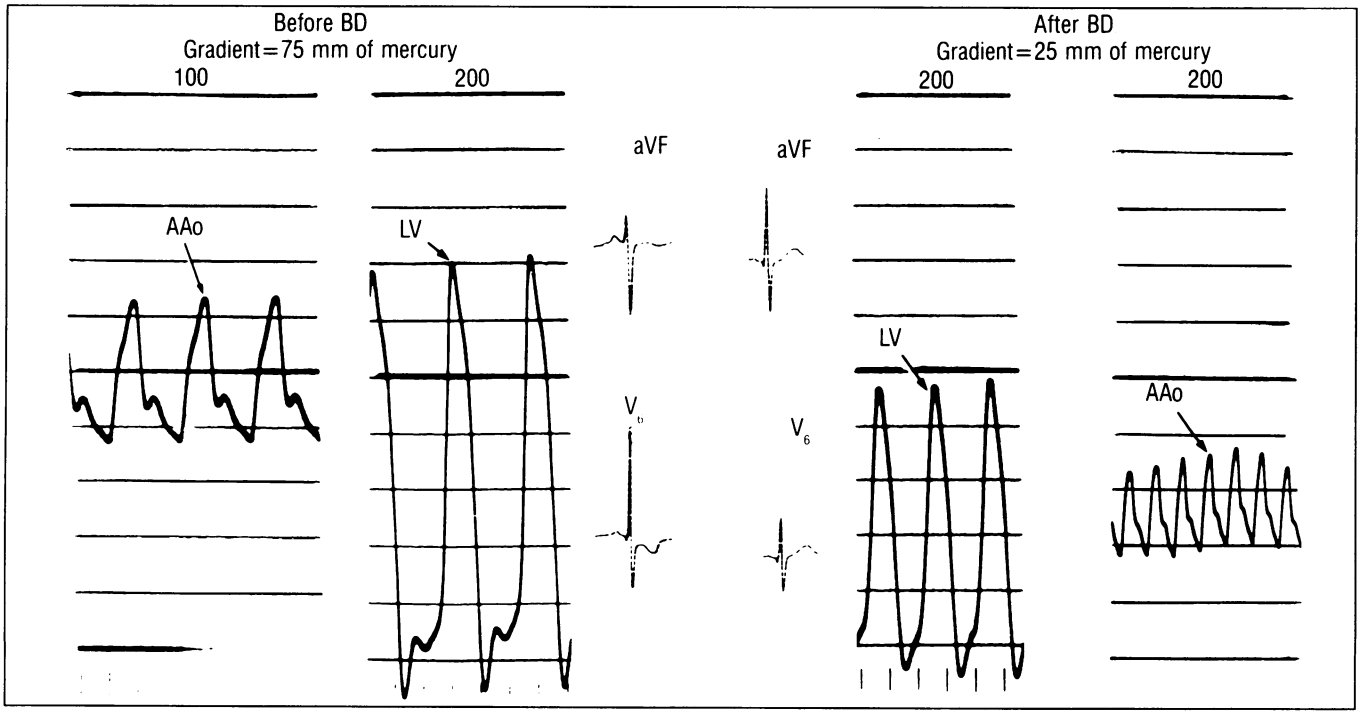

Figure 4.—A 3-month-old infant had balloon dilatation (BD) for aortic stenosis. **Left,** Before the procedure, the ascending aortic (AAo) pressure is 65 mm of mercury, and left ventricular (LV) pressure is 140 mm of mercury. There are inverted T waves in electrocardiographic leads aVF and V_6. **Right,** After BD, T waves are normal, and the LV-AAo gradient is 25 mm of mercury.

Embolus—Insertion or Removal

The insertion of various devices by catheter is a well-established technique in cancer therapy and for obliterating arteriovenous malformations.[48] It is now being used to close a patent ductus arteriosus or atrial septal defect as well as unwanted (residual) postoperative intercirculatory communications.[49] We have used coils to occlude hepatic hemangiomas, pulmonary arteriovenous malformations and aorta-to-pulmonary artery collateral vessels (Figure 7) in six patients with success in each.

Occasionally pieces of intravascular catheters are unintentionally severed, resulting in an embolus of the catheter tip. The retrieval of such foreign body emboli has long been known in adults[50] but is only rarely needed in children. On five occasions, a retrieval of catheter-tip emboli was attempted. In one neonate, the tip of an umbilical venous

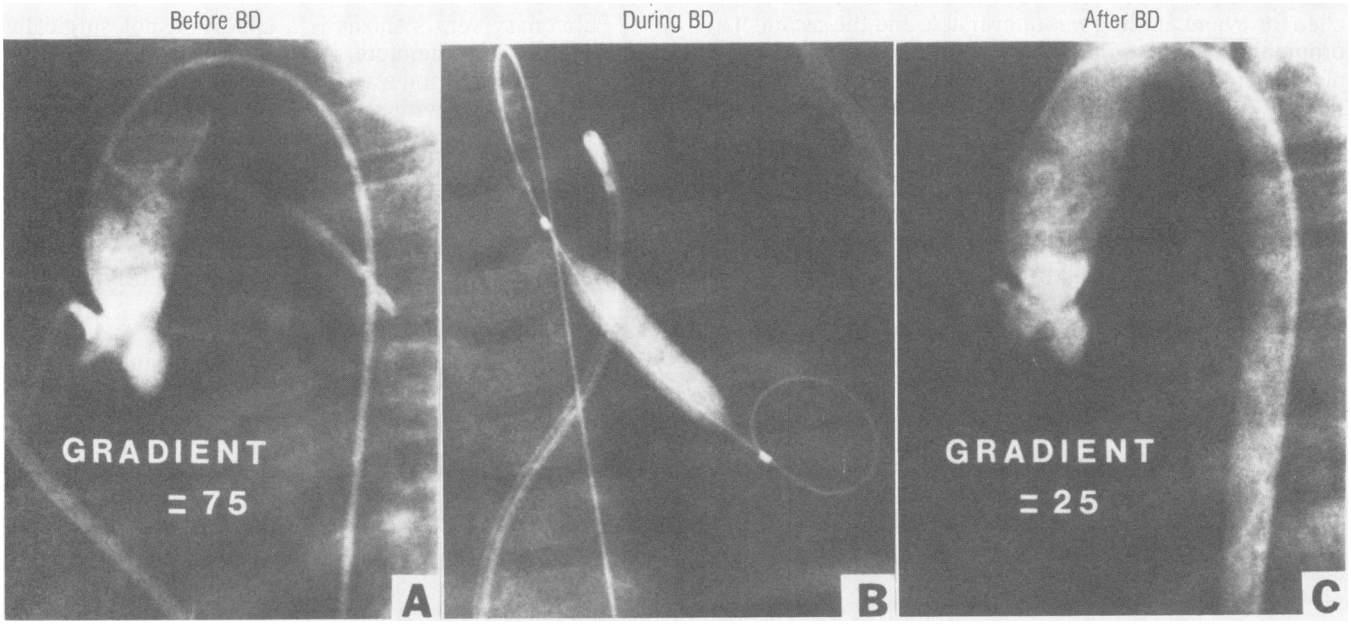

Figure 5.—Aortic valve competence is assessed in a 3-month-old infant having balloon dilatation (BD) for aortic stenosis. **A,** Lateral ascending aortogram shows an eccentric opening and no regurgitation. The gradient is 75 mm of mercury. **B,** A frontal view of the inflated 6-mm balloon shows obliteration of the waist. The loop of extra guide wire in the left ventricle provides an anchor for the BD catheter. **C,** After BD, with the gradient reduced to 25 mm of mercury, supravalvar narrowing is again apparent. The aortic valve continues to be competent.

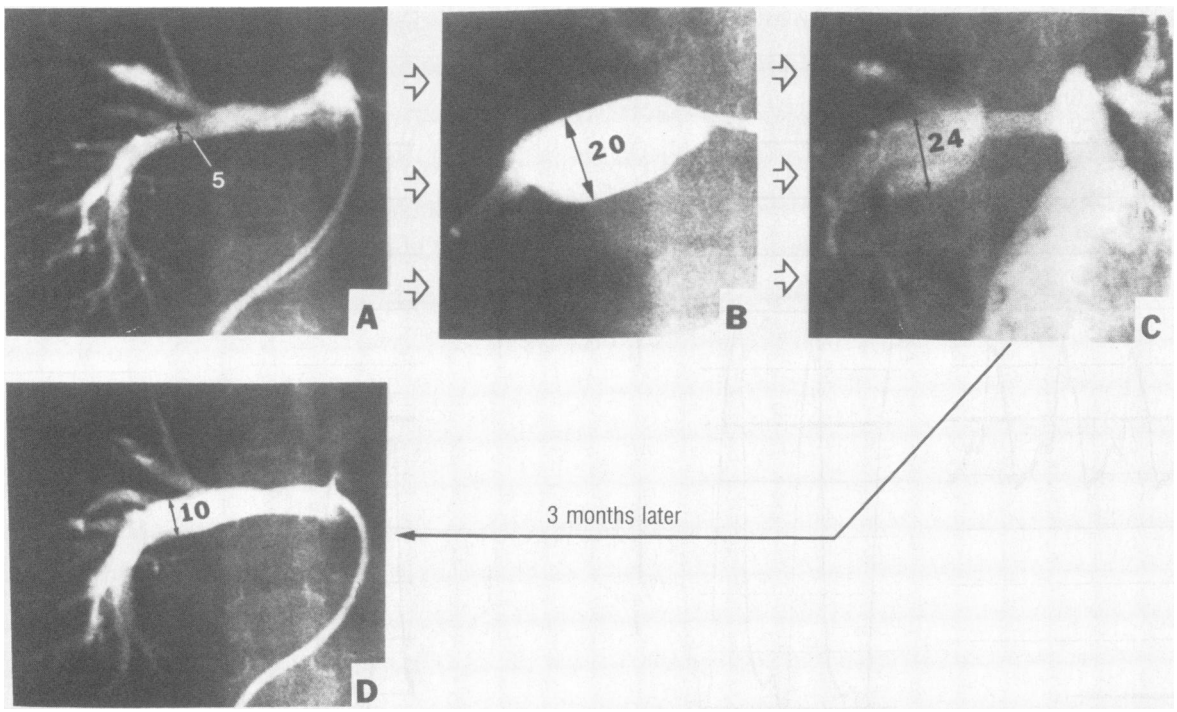

Figure 6.—Balloon dilatation (BD) was done in a 2½-year-old child with congenital peripheral pulmonary artery stenosis. **A,** The distal right lower pulmonary artery measures 5 mm in transverse diameter. **B,** After several BDs with balloons of increasing size, a balloon is used that is 4 times the size of the narrow segment. **C,** There is an "aneurysm" of the distal right pulmonary artery that measures 24 mm. The angiogram is performed in the right ventricle, with the contrast dye injected well away from the area that has been dilated. **D,** 3 months after BD, the right pulmonary artery measures 10 mm—twice the pre-BD size.

catheter had embolized into the liver and could not be retrieved because the umbilical vein was closed. In four other children with noncardiac disorders such as leukemia or hydrocephalus, a surgical procedure would have engendered considerable risk. A basket snare (Figure 8) or biopsy forceps was successfully used to remove an embolus from the pulmonary artery (three patients) and the right atrium (one child).

Therapeutic Cardiac Catheterization

There are several areas where therapeutic cardiac catheterization (TCC) will have considerable effects, such as in medical case planning, the bureaucratic and legislative arena, and in financial matters.

Medical Effects

With the addition of TCC to the armamentarium, planning for some congenital heart lesions has changed. In coarctation of the aorta, most recurrent or residual obstructions can be balloon dilated; therefore, tube graft-type repairs are now avoided. In tetralogy of Fallot, it is now of less concern to leave some residual branch pulmonary artery stenosis. In children with repaired truncus arteriosus in whom stenosis of the valve or distal anastomoses develop, balloon dilatation allows a deferral of conduit changes. Critical semilunar valve stenosis has become a "medical" rather than a surgical emergency.

Until TCC, congenital peripheral pulmonary artery stenosis was a lesion not amenable to therapy. The obstruction usually extends too distal in the lung for surgical repair. With the use of balloon dilatation, internal stents, or both, distal stenoses may be treated by catheter insertion, and residual proximal obstruction may be treated surgically.

Bureaucratic and Legislative Effects

The use of therapeutic cardiac catheterization requires consideration by state regulatory agencies. Without approval of, for instance, California Children's Services in California, third-party payers will not reimburse for the service, precluding the use of the less expensive TCC approach in favor of the more traditional but costlier surgical alternative. As for surgical treatment or cardiac catheterization, standards for training need to be developed. Therapeutic cardiac catheterization is not a procedure that can be read about in a paper and then performed safely. Furthermore, an ongoing monitoring process is necessary to assure quality.

At present, numeric guidelines for diagnostic cardiac catheterizations and for surgical procedures are used to determine accreditation of licensed cardiac centers. The use of TCC will increase the number of catheterizations and decrease the number of operations. Of 640 cardiac catheterizations done in 1987 and 1988, 113 (18%) were done primarily for therapeutic purposes; the number of

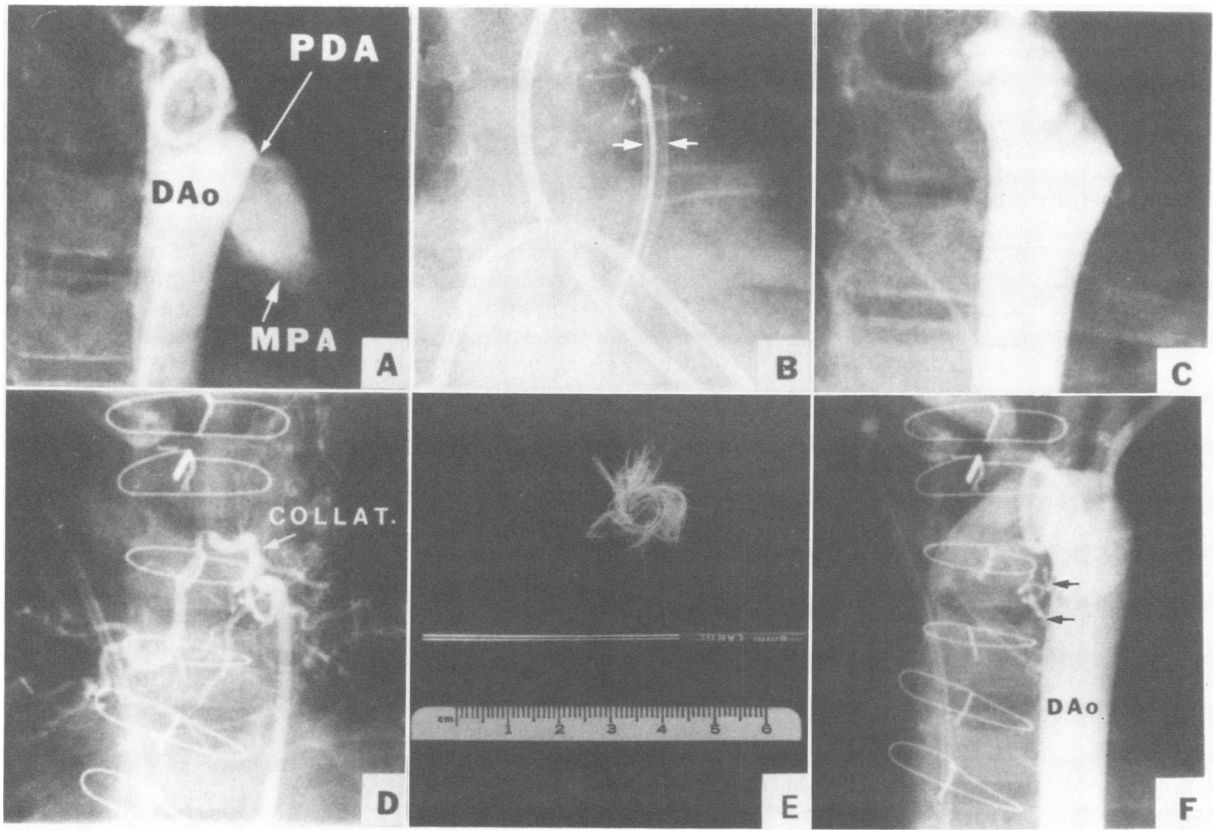

Figure 7.—"Embolotherapy" is used to close a patent ductus arteriosus (PDA) **(A, B,** and **C).** The aortograms in the top row of photos are frontal views. **A and C** (from the same patient), A 12-mm Rashkind occluder was inserted; this is almost invisible radiographically. A 17-mm device from a different patient is shown in **B. A,** Contrast dye injected in the descending aorta (DAo) shows the PDA filling the main pulmonary artery (MPA). **B,** The arrows indicate the large sheath used to guide the collapsed device into position. The device is seen with proximal and distal "legs" expanded, still attached to the delivery system. **C,** Following insertion of the Rashkind occluder, no contrast is seen to pass into the pulmonary artery from injection in the (aortic) ductal infundibulum. A patient with tricuspid atresia had embolotherapy after a Fontan procedure **(D, E,** and **F). D,** A subselective angiogram shows a collateral vessel (collat.) from the descending aorta to the right lung, which creates a left-to-right shunt. **E,** The device at the top of photo is used for embolization; the coil holds the thrombotic strands in place. The lower object is the metal tube used to keep the coil straight for inserting into the delivery catheter. **F,** A descending aortogram after therapeutic cardiac catheterization reveals 2 metallic coils **(black arrows)** placed per catheter that occlude the two right-sided collaterals, one of which was shown in **D.**

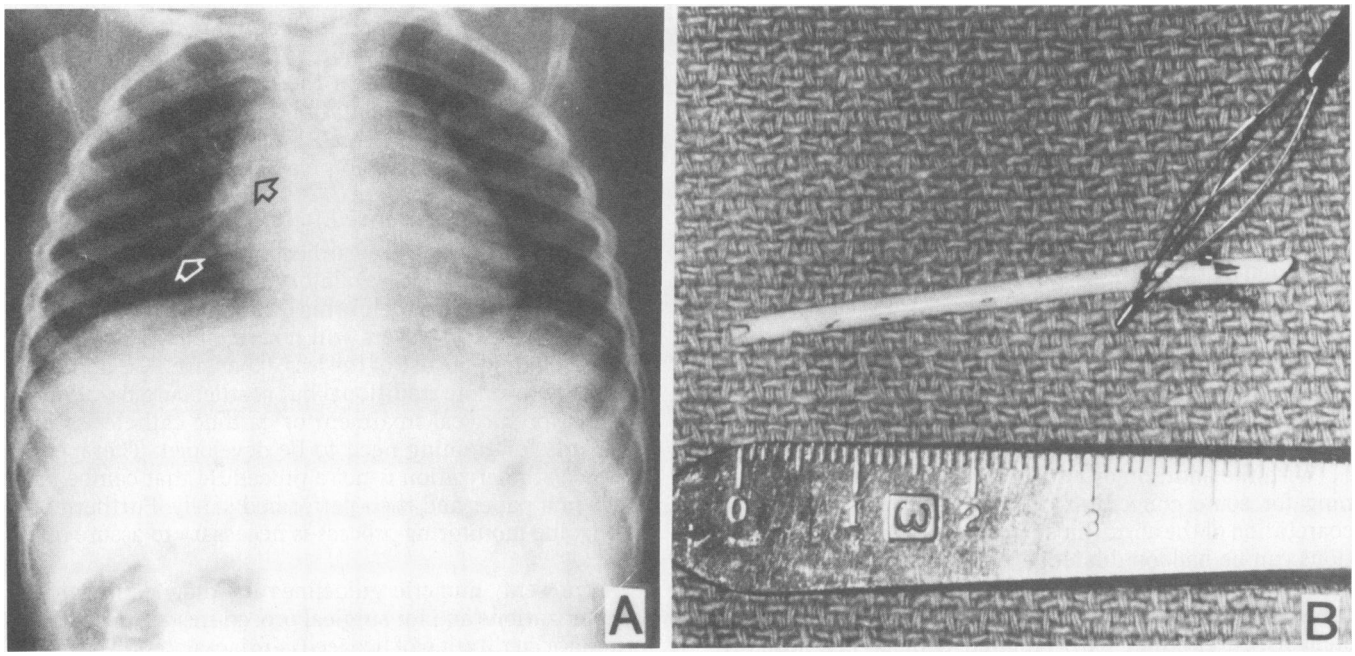

Figure 8.—The photos show catheter retrieval of a catheter-tip embolus. **A,** A segment of Broviac catheter is lodged in the right lower pulmonary artery **(arrows). B,** The Lehman catheter, basket snare, and retrieved catheter-tip embolus are seen.

catheterizations has therefore increased by that number, and the surgical volume has decreased by a corresponding number. These factors also require consideration by state advisory or regulatory agencies.

Fiscal Effects

Treating congenital heart disease is expensive. The surgical repair of "simple" problems such as patent ductus arteriosus can cost around $10,000. The surgical repair of critical semilunar valve stenosis, ventricular septal defect, or tetralogy of Fallot can cost well over $30,000. Balloon dilatation catheters are relatively expensive ($250 to $350 each), and some procedures require more than one. The charges for TCC are usually added to the charges for a diagnostic study, thus increasing the cost of the procedure itself. Although diagnostic catheterizations are routinely done at our center with same-day discharge,[51] patients having TCC stay overnight for observation and postprocedure tests that include a complete blood count, a chest roentgenogram, and an echocardiogram or pulmonary perfusion scan (or both). Thus, a child with pulmonary stenosis who undergoes balloon dilatation spends 1½ days in hospital with an average hospital bill of $3,800 (Figure 9). A comparable patient who had an open-heart procedure for the surgical relief of pulmonary stenosis spent 7½ days in hospital with an average total hospital bill of more than $21,000. The disparity can be even more dramatic in critical neonatal semilunar valve stenosis. Each of our infants who had balloon dilatation of aortic stenosis went home within four days.

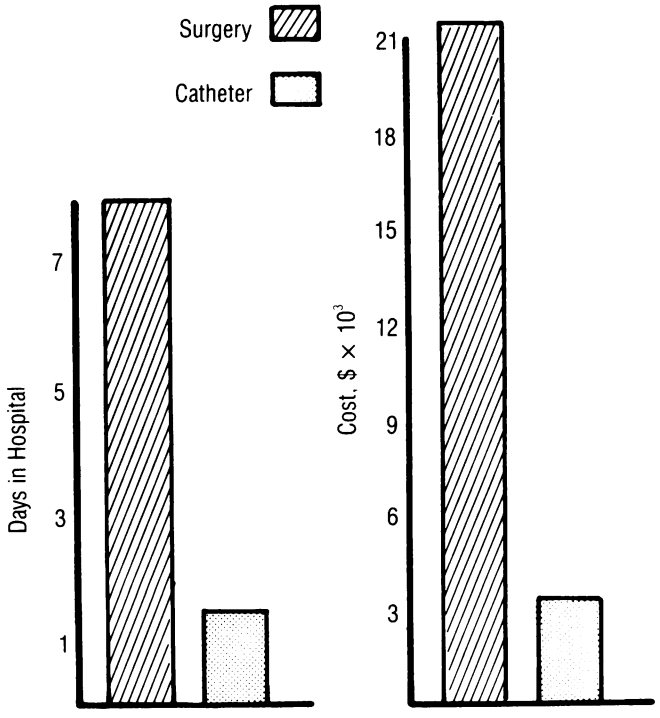

Figure 9.—Balloon dilatation (catheter therapy) is compared with surgical treatment of valvar pulmonary stenosis. In the left graph, the average hospital stay is 7½ days for the surgical relief of pulmonary stenosis; catheter therapy requires 1½ days in hospital. The right graph shows that the cost of an operation is $21,300 (average), compared with $3,800 for balloon dilatation.

Though the case incidence in which TCC will replace surgical treatment is relatively small (approximately 15%), the fiscal impact of TCC can be substantial. For an individual center, the fiscal effect of TCC can be calculated as follows: average number of operations per year × 0.15 × 0.2 equals the percentage decrease in cost of therapy for congenital heart disease. This translates into a large dollar savings for the state when multiplied by the number of centers doing TCC.

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