BALLOON VALVULOPLASTY AND ANGIOPLASTY FOR CONGENITAL AND ACQUIRED HEART DEFECTS IN CHILDREN

P. SYAMASUNDAR RAO, MD

RUBIO AND LIMON LASON described a technique of dilatation of stenotic pulmonary and tricuspid valves in 1954; a decade later, Dotter and Judkins described a technique of balloon dilatation of atherosclerotic lesions. Balloon dilatation techniques were revived in the mid-1970s when Gruntzig and associates dilated coronary artery stenosis. Similar techniques have also been used in dilating stenotic lesions in renal, iliac, and femoral arteries. More recently, balloon dilatation techniques have been applied in infants and children to relieve congenital, acquired, and postoperative stenotic lesions. Although the initial description of balloon valvuloplasty is by a pullback or dynamic technique as suggested by Rubio and Limon Lason in 1954 and by Semb and his associates in 1979, a static dilatation technique, as described by Kan and her associates, is commonly used. The purpose of this review is to present the state-of-the-art of balloon dilatation of stenotic lesions in infants, children, and adolescents; personal experience with balloon dilatation in approximately 150 infants, children, and adolescents, including our previous publications and that reported in literature will be utilized as supportive material.

Indications

The indications for surgical pulmonary valvotomy are reasonably clear; patients with moderate to severe degree of stenosis, irrespective of the symptoms, are candidates for surgical relief of the obstruction. The indications for balloon valvuloplasty appear less clear and rarely defined. Careful examination of all the available studies revealed that many patients with what may be considered mild pulmonic stenosis (natural history study definition: gradient < 25 mm Hg = trivial, 25 to 49 mm Hg = mild, 50 to 79 mm Hg = moderate, and ≥ 80 mm Hg = severe) underwent balloon valvuloplasty. Review of the results of balloon valvuloplasty in these patients with mild stenosis revealed that residual right ventricular peak systolic pressures at follow-up were 75 ± 18% of prevavuloplasty values. Furthermore, natural history studies of pulmonic stenosis indicated that mild pulmonary stenosis remains mild on follow-up. Therefore, the advisability of balloon valvuloplasty for mild obstruction could be questioned. My own recommendations are to consider the indications for balloon valvuloplasty to be the same as those used for surgical valvuloplasty and that balloon dilatation should not be performed in patients with gradients less than 50 mm Hg. Because noninvasive Doppler estimates of pulmonary valve gradients are reasonably accurate, these patients with mild stenosis could be followed and once the Doppler estimate of the gradient is in excess of 50 mm Hg, they could undergo balloon valvuloplasty. Previous surgical pulmonary valvuloplasty is not a contraindication for balloon valvuloplasty. Some investigators consider dysplastic pulmonary valves as a relative contraindication for balloon valvuloplasty but based on results of other workers and our data presented elsewhere, balloon valvuloplasty is the initial treatment of choice; perhaps, large balloons to produce balloon/annulus ratio of 1.4 to 1.5 should be used. In conclusion, moderate to severe valvar pulmonic stenosis (gradient ≥ 50 mm Hg), irrespec
tive of previous surgical intervention and pulmonary valve
dysplasia, is an indication for percutaneous balloon
pulmonary valvuloplasty.
The indications for balloon coarctation angioplasty is
hypertension and/or congestive heart failure,11,13,15 very
similar to indications for surgery. Although there is some
concern with regard to development of aneurysms40-44
following balloon angioplasty of native coarctation and
postoperative recurrent coarctations, some
authors11,13,15,41,42,45 recommend this procedure. This is
particularly true in the neonate and small infant because of
high morbidity and mortality as well as a high recurrence
rate with surgery.46-48 The issue of balloon angioplasty of
native coarctations is, at the present, unsettled and
controversial. With regard to an older child with native
coarctation, because of concern for developing aneurysms,
this procedure should probably be performed at selected
centers with expertise in
this lesion; its general use should be delayed until longer
follow-up results and reports of follow-up on a larger
number of patients have been studied.
Due to the fact that the aortic valvar gradient appears to
decrease to approximately 50% of prevalvuloplasty
values49,50 and because of lack of long-term follow-up
results documenting its effec
tiveness, one could question the routine use of balloon
aortic valvuloplasty. When these issues are settled, the
indications for balloon aortic valvuloplasty should be
similar to those used for surgical valvotomy. Despite a
high complication rate, critical aortic stenosis in the neon
te and young infant is an indication for balloon therapy
because of high morbidity and mortality with surgical
intervention. A stenosed branch pulmonary artery,
producing a right ventricular or pulmonary artery systolic
pressure in excess of one half the systemic pressure, is an
indication for balloon dilatation.51,52 In an infant with cyanotic congenital heart defect with
pulmonary oligemia, balloon pulmonary valvuloplasty is
an effective alterntive to surgical systemic artery-to-
pulmonary artery anastomosis if the infant's size and/or
anatomy are not suitable for surgical correction. We would
suggest multiple obstructions in the pulmonary
outflow tract as a prerequisite in order to avoid flooding the
lungs.
The experience with dilatation of other stenotic lesions is
limited and therefore definitive guidelines cannot be drawn.
But, by and large, the indications for balloon therapy should
be the same as those used for surgical intervention.
Additional indications for balloon dilatation would include
patients who cannot tolerate anesthesia and/or surgery
because of other medical reasons.

**Technique**

The diagnosis and assessment of the obstructive lesions of the
heart are made by the usual clinical, roentgenographic,
electrocardiographic, and echo-Doppler data. Once a
moderate to severe obstruction is diagnosed, cardiac
catheterization and cineangiography are performed
percutaneously to confirm the clinical impression and to
consider for balloon dilatation of the stenotic lesion. The
indications for catheter intervention (as described above) are
usually those prescribed for surgical intervention. Once
balloon dilatation is decided upon, (1) a No. 4- to 7-French
end-hole (or A-2) catheter is introduced percutaneousl y,
either into the femoral artery or vein and advanced across the
stenotic lesion, (2) a 0.014 to
\[0.038\text{\ inch} \]
inch guide wire is passed
through the catheter into the vessel or cardiac chamber
beyond the stenotic lesion, (3) a No. 4- to 9-French balloon
dilatation catheter is advanced over the guide wire and the
balloon is positioned across the stenotic lesion, and (4) the
balloon is inflated with diluted contrast material to
approximately 3 to 5 atmospheres of pressure. The
recommended duration of inflation is 5 seconds. Usually a
total of 3 to 4 balloon inflations are performed, 5 minutes
apart. We use a double balloon technique (two balloons
simultaneously inflated across the stenotic lesion) when the
stenotic lesion is too large to dilate with a commercially
available single balloon. The recommended size of the
balloon varies with the type of the stenotic lesion to be
dilated, e.g., 1.2 to 1.5 times the size of the pulmonary valve
annulus in pulmonary stenosis,18 no larger than the size of the
aortic valve annulus for aortic stenosis,53 2.0 to 2.5 times the
size of the coarcted aortic segment but no larger than the
descending aorta at the level of the diaphragm,11,35,54 and 3 to
4 times the size of
tive of previous surgical intervention and pulmonary valve dysplasia, is an indication for percutaneous balloon pulmonary valvuloplasty.

The indications for balloon coarctation angioplasty is hypertension and/or congestive heart failure.13,15 Very similar to indications for surgery. Although there is some concern with regard to development of aneurysms40-44 following balloon angioplasty of native coarctation and postoperative recurrent coartations, some authors11.13.15.41.42.45 recommend this procedure. This is particularly true in the neonate and small infant because of high morbidity and mortality as well as a high recurrence rate with surgery.46-48 The issue of balloon angioplasty of native coarctations is, at the present, unsettled and controversial. With regard to an older child with native coarctation, because of concern for developing aneurysms, this procedure should probably be performed at selected centers with expertise in this lesion; its general use should be delayed until longer follow-up results and reports of follow-up on a larger number of patients have been studied.

Due to the fact that the aortic valvar gradient appears to decrease to approximately 50% of prevalvuloplasty values49,50 and because of lack of long-term follow-up results documenting its efficaciness, one could question the routine use of balloon aortic valvuloplasty. When these issues are settled, the indications for balloon aortic valvuloplasty should be similar to those used for surgical valvotomy. Despite a high complication rate, critical aortic stenosis in the neonate and young infant is an indication for balloon therapy because of high morbidity and mortality with surgical intervention. A stenosed branch pulmonary artery, producing a right ventricular or pulmonary artery systolic pressure in excess of one half the systemic pressure, is an indication for balloon dilatation.51,52 Although long-term results are not known, inaccessibility for surgical intervention would make balloon intervention a therapy of choice.

In an infant with cyanotic congenital heart defect with pulmonary oligemia, balloon pulmonary valvuloplasty is an effective alternate to surgical systemic artery-to-pulmonary artery anastomosis if the infant's size and/or anatomy are not suitable for surgical correction. We would suggest multiple obstructions in the pulmonary outflow tract as a prerequisite in order to avoid flooding the lungs.

The experience with dilatation of other stenotic lesions is limited and therefore definitive guidelines cannot be drawn. But, by and large, the indications for balloon therapy should be the same as those used for surgical intervention. Additional indications for balloon dilatation would include patients who cannot tolerate anesthesia and/or surgery because of other medical reasons.

**Technique**

The diagnosis and assessment of the obstructive lesions of the heart are made by the usual clinical, roentgenographic, electrocardiographic, and echo-Doppler data. Once a moderate to severe obstruction is diagnosed, cardiac catheterization and cineangiography are performed percutaneously to confirm the clinical impression and to consider for balloon dilatation of the stenotic lesion. The indications for catheter intervention (as described above) are usually those prescribed for surgical intervention. Once balloon dilatation is decided upon, (1) a No. 4- to 7-French end-hole (or A-2) catheter is introduced percutaneously, either into the femoral artery or vein and advanced across the stenotic lesion, (2) a 0.014 to 0.038 inch guide wire is passed through the catheter into the vessel or cardiac chamber beyond the stenotic lesion, (3) a No. 4- to 9-French balloon dilatation catheter is advanced over the guide wire and the balloon is positioned across the stenotic lesion, and (4) the balloon is inflated with diluted contrast material to approximately 3 to 5 atmospheres of pressure. The recommended duration of inflation is 5 seconds. Usually a total of 3 to 4 balloon inflations are performed, 5 minutes apart. We use a double balloon technique (two balloons simultaneously inflated across the stenotic lesion) when the stenotic lesion is too large to dilate with a commercially available single balloon. The recommended size of the balloon varies with the type of the stenotic lesion to be dilated, e.g., 1.2 to 1.5 times the size of the pulmonary valve annulus in pulmonary stenosis,18 no larger than the size of the aortic valve annulus for aortic stenosis, 53 2.0 to 2.5 times the size of the coarcted aortic segment but no larger than the descending aorta at the level of the diaphragm, 11.15.54 and 3 to 4 times the size of
the pulmonary arterial or venous stenotic lesions. The size of the valve annulus or vessel can be measured by echocardiographic techniques and re-measured from the frozen video images of the cineangiograms just prior to balloon dilatation. Attention should be paid to avoid parallax error, correctly identify and measure the valve annulus, and accurately correct for magnification, especially when the valve or vessel size is small. When dilatation involves left heart structures, a single intravenous dose of heparin 100 units/kg (maximum 2000 units) is administered after introduction of the arterial catheter. The heparin is neither continued nor its effect reversed after the procedure. Measurement of pressure gradients across the stenotic lesions and angiographic demonstration of the relief of obstruction are recorded.

Mechanism of Valvuloplasty and Angioplasty

Inflation of a balloon placed across an obstructive lesion exerts radial forces upon the stenotic lesion without any axial component. Several physical principles of the "dilating force" are important in the mechanism of action and should be understood for successful application of the balloon dilatation technique: (1) for the same pressure, there is a greater dilating force for a larger diameter balloon than a smaller diameter balloon; (2) for the same pressure, longer balloons have greater dilating force than shorter balloons; (3) for the same size balloon, higher is the inflation pressure, greater is the dilating force; these are related in a linear fusion; (4) for the same pressure, a tighter stenotic area will receive a greater dilating force than a less tight stenosis; (5) for the same pressure, a large stenotic area will receive a higher dilating force when compared to a smaller stenotic area; and (6) high inflation pressures will not significantly increase the diameter of the balloon because the balloon material (especially treated polyethylene in most pediatric dilatation balloons) does not expand due to the fact that "yield strength" (the force at which permanent deformation of the material occurs) and "ult

Mechanism of Valvuloplasty and Angioplasty

Inflation of a balloon placed across an obstructive lesion exerts radial forces upon the stenotic lesion without any axial component. Several physical principles of the "dilating force" are important in the mechanism of action and should be understood for successful application of the balloon dilatation technique: (1) for the same pressure, there is a greater dilating force for a larger diameter balloon than a smaller diameter balloon; (2) for the same pressure, longer balloons have greater dilating force than shorter balloons; (3) for the same size balloon, higher is the inflation pressure, greater is the dilating force; these are related in a linear fusion; (4) for the same pressure, a tighter stenotic area will receive a greater dilating force than a less tight stenosis; (5) for the same pressure, a large stenotic area will receive a higher dilating force when compared to a smaller stenotic area; and (6) high inflation pressures will not significantly increase the diameter of the balloon because the balloon material (especially treated polyethylene in most pediatric dilatation balloons) does not expand due to the fact that "yield strength" (the force at which permanent deformation of the material occurs) and "ultine tensile strength" (the force necessary to break the material) of the balloon material are very close to each other.

Based on these principles and the experience with balloon dilatations in children, we now routinely perform sequential balloon inflation with 3, 4, and 5 atmospheres of pressure of 5 second duration, 5 minutes apart. If waisting of balloon could not be abolished, then we sequentially increase pressure of inflation to 6, 7, and 8 atmospheres of pressure; this was required on only two occasions (both native coarctations) out of a total experience of 150 balloon dilatations in children.

The mechanism of valvuloplasty was assessed by Walls and his associates by inspection of valve mechanism by direct vision at surgery; they found tearing of valve raphae, tearing of the valve leaflets, and avulsion of the valve leaflets, and all are conceivably the mechanisms by which relief of pulmonary or aortic valve obstruction can occur. Direct visual observations by other authors, though limited in numbers, and echocardiographic observations also indicate similar mechanism. The circumferential dilating force exerted by balloon inflation is likely to rupture (tear) the weakest part of the valve mechanism. It is likely that the fused commissures are the weakest links that can be broken with balloon dilatation. However, in a given patient, when the fused commissures are strong and cannot be torn, tears in the valve cups or avulsion of the valve leaflets can occur. The latter events may cause more severe semilunar valve insufficiency.

Lock and his associates created aortic coarctations and branch pulmonary artery stenoses and balloon-dilated the stenotic lesions in order to determine the mechanism of balloon angioplasty. Linear intimal tears were observed in both lesions; they were located at or near the area of maximal narrowing in branch pulmonary artery stenotic lesions while they were located in the nonoperated aortic wall in experimentally produced aortic coarctations. The intimal tears were noted to extend into the media with intramedial hemorrhage. No evidence for adventitial rupture was observed. These mechanisms of relief may be similar in postoperative recoarctations but may not be applicable to native, previously unoperated stenotic lesions. The presence of intimal and medial tears following dilatation of human
Valvoplasty and Angioplasty

Aortic coarctation were also observed by several workers, although these were isolated single cases. Thus, the mechanism of relief of arterial obstructions is by tearing of intima and media.

Immediate and Follow-up Results

Isolated Valvar Pulmonic Stenosis

Several groups of workers, including our group have reported excellent immediate relief of pulmonic valve obstruction following balloon valvuloplasty. Reduction of pulmonary valvar peak systolic pressure gradient and right ventricular systolic pressure without change in the cardiac index has been observed. The width of the jet of the contrast material through the pulmonary valve, as visualized in the lateral view of the cineangiogram (Figure 1), increases. Less doming and much more "free" movement of the pulmonary valve leaflets occur, following the valvuloplasty in each case. Surgical intervention is avoided in most, if not all, patients. Most patients are discharged home within 24 to 48 hours following the procedure.

Although balloon pulmonary valvuloplasty is used most frequently in childhood, it has also been used successfully in neonates. The experience with pulmonary valvuloplasty in the neonate with critical pulmonary stenosis is limited, and the series with the largest numbers contain only a few patients. The procedure is more technically difficult but can be accomplished by use of endhole balloon wedge catheters, small sized, HiTorque guide wires, and low profile balloon catheters. The pulmonary outflow tract occlusion during valvuloplasty is well tolerated while continuous administration of prostaglandins maintains ductal patency. The overall result is perhaps not as favorable as in children. Right ventricular hypoplasia, severe infundibular obstruction, pulmonary valve ring hypoplasia, and pulmonary valvar dysplasia may tend to affect adversely the results of valvuloplasty in the neonate with critical pulmonary stenosis.

Several authors recatheterized 6 to 23 patients, 1 week to 17 months following balloon valvuloplasty, and reported 14% to 33% recurrence. We restudied 36 children, 6 to 34 months (mean, 11.0 months), following balloon valvuloplasty. Most studies show continued relief or

Figure 1. Selected frames from the lateral views of right ventricular (RV) cineangiogram prior to (A) and after (B) balloon pulmonary valvuloplasty. Note extremely thin jet prior to balloon dilatation (A) which increased to a much wider jet (arrow) after valvuloplasty (B) opacifying the main pulmonary artery (MPA); C, catheter.

improvement of the pulmonary valve gradient. Some children with required repeat balloon valvuloplasty with larger balloons (Figure 2), pulmonary valvar gradients were successfully reduced.

LOW-UP RESULTS OF BALLOON PULMONARY VALVULOPLASTY

2. Longitudinal follow-up data following balloon pulmonary valvuloplasty. In 29 children (solid lines), the peak systolic pressure gradient of the valve improved or remained unchanged at follow-up (FU) when compared with the pre-BPY gradient. In seven children (interrupted lines), the gradient was high or increased; five of these children underwent repeat valvuloplasty with larger balloons with improvement in pulmonary valvar gradients. A significant fall in gradient in each patient.

*The procedure was successfully performed in 15th tetralogy of Fallot, transposition of the great arteries, ventricular septal defect and valvar and subvalvar pulmonary stenosis, critical pulmonary stenosis with intact ventricular septum and hypoplastic right ventricle, and ventricular right arterial oxygen saturation, pulmonary blood flow, pulmonary-to-systemic flow ratio, and pulmonary artery pressures following valvuloplasty. None developed hypoxemia. The procedure was successfully performed in tetralogy of Fallot, transposition of the great arteries, ventricular septal defect and valvar and subvalvar stenosis, critical pulmonary stenosis with intact ventricular septum and hypoplastic right ventricle, and ventricular right arterial oxygen saturation, pulmonary blood flow, pulmonary-to-systemic flow ratio, and pulmonary artery pressures following valvuloplasty. None developed hypoxemia.*

The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. Follow-up results, several months after valvuloplasty, reveal that all infants were thriving with increased hypoxemia and polycythemia, and the immediate balloon valvuloplasty improvement persisted or improved further in three patients. A significant rise in the arterial oxygen saturation, pulmonary blood flow, and pulmonary artery pressure were noted. None of the patients had elev in pulmonary systolic pressure.16,64 Successful correction in tetralogy of Fallot patients or further surgery in other patients was accomplished during the follow-up period.64 These data suggest that pulmonary valvuloplasty is an excellent palliation of pulmonary oligemia in cyanotic defects, thus, avoiding the risks of immediate surgical intervention for a better result of eventual total surgical correction. Follow-up results, several months after valvuloplasty, reveal that all infants were thriving with increased hypoxemia and polycythemia, and the immediate balloon valvuloplasty improvement persisted or improved further in three patients. A significant rise in the arterial oxygen saturation, pulmonary blood flow, and pulmonary artery pressure were noted. None of the patients had elevated pulmonary systolic pressure.16,64 Successful correction in tetralogy of Fallot patients or further surgery in other patients was accomplished during the follow-up period.64 These data suggest that pulmonary valvuloplasty is an excellent palliation of pulmonary oligemia in cyanotic defects, thus, avoiding the risks of immediate surgical intervention for a better result of eventual total surgical correction.

on these data, the intermediate-term follow-up results are encouraging and lead us to recommend balloon valvuloplasty as the choice for treatment of isolated valvar pulmonary stenosis. Further refinement in the technique may decrease or abolish the recurrence rate. Despite these good results, much longer term follow-up data are necessary to further confirm the effectiveness of balloon pulmonary valvuloplasty for relief of pulmonary stenosis.

on pulmonary valvuloplasty for infants with cyanotic heart disease, pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al. The indications for valvuloplasty in infants with cyanotic heart defects which were not amenable to total correction at the age and size at presentation but at the same time palliation of pulmonary oligemia was used by USL6 and Boucek et al.
the systemic hypertension. The femoral pulses, which had been either absent or markedly reduced and delayed (when compared to brachial pulses), become palpable with increased pulse volume following angioplasty. Immediate surgical intervention is avoided.

Balloon angioplasty of aortic coarctation appears to be particularly useful in neonates and small infants.\13,59,66,67\ Several groups of workers\40-43,45,54,65\ restudied 7 to 14 patients, 1 to 31 months following angioplasty, and reported 14% to 31% recoarctation and 8% to 55% aneurysmal formation. We studied 20 children, 6 to 30 months (mean, 11.6 months), following balloon angioplasty.\68\ Most studies showed continued improvement. Some children developed recoarctation. Sequential pressure gradients across the coarctation and the sizes of the coarcted segment for our group of patients are shown in Figure 3. These children with recoarctation were treated successfully with repeat balloon angioplasty or surgical resection. The aneurysms that were reported in some of the previous studies,\40-43\ though not found by us,\15,68\ are of concern and should temper the recommendation of balloon angioplasty of unoperated coarctations. A high incidence of recurrence following balloon angioplasty in young infants is comparable to that seen with surgical resection of aortic coarctation.\46-48\ Despite this, we continue to recommend balloon angioplasty of native aortic coarctation in infants\12,13,15\ as the initial treatment of choice because balloon dilatation offers a safer alternative to surgical repair in infants. With balloon angioplasty, surgery may be avoided completely or postponed until the child is larger and the risk of death and recoarctation\46-48\ associated with surgery are less.

Because of the concern with the development of aneurysms,\40-43\ balloon angioplasty of native coarctations in children should probably be performed at selected centers so as to gain insight into the magnitude of the problem and natural history of aneurysms. Until this information is available, this procedure should not be routinely performed in children beyond infancy.

Figure 3. Panels A and B show longitudinal follow-up data following balloon coarctation angioplasty (BA). In 13 children (solid lines), the gradient across the coarctation of the aorta and the size of the coarcted segment either improved or remain unchanged when compared to immediate postangioplasty values. In seven children (interrupted lines), the gradient increased with or without change in the size of the coarcted aortic segment. Two of these children underwent repeat BA with good results; another two children underwent surgical resection; and three remaining children did not have discrete narrowing and therefore neither surgery nor balloon angioplasty were recommended.


Recoarctation Following Previous Surgery

Although there are very few reports of balloon angioplasty for recoarctations,\44,54,60,67\ each report has good results. Despite the limited experience, a consensus is rapidly emerging that balloon angioplasty is the procedure of choice for recoarctations.\34, 60, 70\ Hemodynamic and angiographic relief of the obstruction and improvement
in systemic hypertension occur. Relief of recoarctation by angioplasty occurs independent of the type of prior surgical procedure (subclavian or dacron patch angioplasty, end-to-end anastomosis, or repair of aortic interruption).

Follow-up catheterization and angiographic follow-up are available in only a few patients. Lock et al. found recoarctation in the single patient whom they restudied six months following the first dilatation; this patient required a second angioplasty which had good results. Saul and his associates restudied five patients; two of these patients developed aneurysms and an additional patient developed recoarctation. Alien et al. restudied 6 patients and found no recurrences. From our own series, 3 patients underwent repeat study at 6, 8, and 22 months following balloon angioplasty. The immediate postdilatation gradients of 20, 10, and 3 mm Hg respectively fell to 8, 7, and 2 mm Hg. None of these three patients developed aneurysms. Based on the available data, it appears that recoarctations, following all types of repairs of aortic coarctation and arch interruptions, can be balloon-dilated with excellent immediate results. Follow-up results are available in only a few patients, and the development of aneurysms at follow-up in the 2 out of 5 patients studied is of great concern. Occurrence of aneurysms following surgery has been documented. Therefore, it is difficult to be sure whether these aneurysms are related to surgery or balloon angioplasty.

**Aortic Stenosis**

Balloon aortic valvuloplasty had been performed by several groups of workers and the results, though acceptable, are not as good as those following pulmonary valvuloplasty; generally the valvar gradient is reduced to 50% of pre-valvuloplasty values. No significant increase in aortic insufficiency occurs. Applicability of this technique to severe or critical aortic stenosis in the neonate and small infant is quite attractive because of high surgical mortality at initial or repeat aortic valvotomy.

Although acute results of balloon aortic valvuloplasty and clinical follow-up are available from many studies, follow-up catheterization has not been extensively documented. Lababidi et al. reported cardiac catheterization results in 6 patients, 3 to 9 months following balloon aortic valvuloplasty, and found that no significant restenosis occurred. Sholler et al. recatheterized 16 patients, 1 to 25 months after valvuloplasty, and found significant residual peak-to-peak aortic valve gradients (45 ± 29 mm Hg).

It may be concluded that balloon aortic valvuloplasty, despite modest decrease in aortic gradients and potential for arterial complications, may have a place in the treatment of aortic valve stenosis because of high chance for recurrence following surgical valvuloplasty. Miniaturization of balloon/catheter systems and documentation of long-term follow-up results of balloon valvuloplasty are essential prior to using this technique as a preferred alternative to surgical valvulotomy.

**Branch Pulmonary Artery Stenosis**

Balloon angioplasty of peripheral pulmonary artery stenosis, congenital or acquired (postsurgical), has been performed by Lock and his associates. These lesions are difficult to dilate adequately. In Lock's extensive experience with these lesions, the success rate of angioplasty is approximately 55%, even when criteria for success have been defined as an increase in diameter of the stenosed area > 50% or increased blood flow to the affected side. Our personal experience is limited, with improvement in one of the two patients in whom we performed this procedure. There has not been adequate documentation of long-term follow-up of the dilatations of the peripheral pulmonary artery stenotic lesions; three of the seven restudied patients developed restenosis. Despite relatively low success (when compared to other stenotic lesions) and a high complication rate, balloon angioplasty remains the procedure of choice for relief of peripheral pulmonary artery stenotic lesions because of their inaccessibility for surgical relief.

**Other Lesions**

Balloon dilatation techniques have been applied to other congenital and postoperative stenotic lesions, namely, mitral and tricuspid valve stenosis, discrete subaortic membranous stenosis, pulmonary vein stenosis, patent ductus
arteriosus (either for improving pulmonary oligemia or for improving systemic perfusion), venal caval or interatrial baffle obstruction following Mustard or Senning operation for transposition of the great arteries, supravalvar pulmonic stenosis following arterial switch operation for transposition of the great arteries, stenosed Blalock-Taussig shunt, and stenosed bioprosthetic valves in pulmonary, aortic, mitral, and tricuspid positions. However, the success of balloon angioplasty varied, depending upon the lesion dilated and the technique of dilatation used. Discussion of these details is beyond the scope of this paper.

Complications

Immediate

Complications during and immediately after balloon valvuloplasty/angioplasty have been remarkably minimal. Transient bradycardia, premature beats, and decrease in the systemic pressure during balloon inflation have been uniformly noted by all workers, particularly with valvar dilatations. These complications return rapidly back to normal following balloon deflation. The use of double balloons and of a trifoil or a bifoil balloon to allow blood to egress from the ventricle during balloon inflation, and shorter periods (5 seconds) of inflation, have been advocated to reduce the systemic hypotension. Having had experience with each of these techniques, the author feels that short periods of balloon inflation (5 seconds or less) are most efficacious without compromising immediate or follow-up results.

Blood loss, requiring transfusion, has been reported in many studies. Complete right bundle branch block, transient left bundle branch block and other transient electrocardiographic abnormalities, transient or permanent heart block, ventricular fibrillation (particularly with aortic valvuloplasty), cerebrovascular accident, loss of consciousness, cardiac arrest, convulsions, transmural tears with vessel wall perforation, balloon rupture at high inflation pressures, tricuspid valve papillary muscle rupture, severe infundibular obstruction (following pulmonary valvuloplasty) requiring propranolol administration and/or surgical intervention, aortic insufficiency or mitral valve tears (following aortic valvuloplasty), and hypertension with a forme fruste postcoarctectomy syndrome, though rare, have been reported. Femoral artery thrombosis requiring heparin, streptokinase, or thrombectomy occurred in 39% (12 of 31) of patients undergoing balloon dilatation of aortic coarctation or stenosis, while such a complication occurred in only 2.2% of arterial catheterizations, not involving balloon dilatation. Deaths associated with balloon dilatation have been reported after angioplasty of peripheral pulmonary artery stenosis, of coarctation of the aorta, and of aortic stenosis; these were either related to vessel wall rupture, occlusion of extremely critical obstruction, or ventricular fibrillation. Fellows and his associates carefully analyzed complications of catheter therapy over a three-year-period and reported 12% acute complications; 6% were major and 6% were minor. The mortality rate was 0.7%. The complication rate appears to be related to the age of the patient and the type of lesion dilated. Patients younger than six months had a higher rate of complication than in older children. Dilatation of recurrent coarctations appeared to have the lowest incidence of complications (4%) while aortic valvuloplasty had the highest complication rate (40%). Some of these complications may be unavoidable. However, meticulous attention to the details of the technique, use of an appropriate length of the balloon, avoidance of extremely high inflation pressures, and short inflation/deflation cycles may prevent or reduce the complications.

Fellows and his associates carefully analyzed complications of catheter therapy over a three-year-period and reported 12% acute complications; 6% were major and 6% were minor. The mortality rate was 0.7%. The complication rate appears to be related to the age of the patient and the type of lesion dilated. Patients younger than six months had a higher rate of complication than in older children. Dilatation of recurrent coarctations appeared to have the lowest incidence of complications (4%) while aortic valvuloplasty had the highest complication rate (40%). Some of these complications may be unavoidable. However, meticulous attention to the details of the technique, use of an appropriate length of the balloon, avoidance of extremely high inflation pressures, and short inflation/deflation cycles may prevent or reduce the complications.

Halter monitoring for 24 hours following balloon valvuloplasty revealed premature ventricular contractions (grade 1, Lawn criteria) in one-third of the 12 patients who have been studied. It is not clear from this study whether the premature beats were present prior to valvuloplasty and for how long after valvuloplasty that the premature beats persisted. Transient prolongation of the QTc interval following balloon pulmonary valvuloplasty may be a potential hazard for developing R-on-T phenomenon in children with ventricular ectopy. The Holter findings of premature beats following valvuloplasty may have significance in the light of prolongation of QTc interval. However, no patients from our series or many other studies have been known to develop ventricular arrhythmias, although two
cases of sudden death from ventricular fibrillation shortly after balloon angioplasty of aortic coarctation were reported. Whether these arrhythmias are related to QTc prolongation or not, is not known. However, patient monitoring following balloon valvuloplasty/angioplasty is warranted.

Complications at Follow-up

With regard to complications at intermediate-term follow-up, femoral vessel occlusion, pulmonary valve insufficiency, aneurysms at coarctation dilatation site, and recurrence of obstruction have been noted. Anywhere between 10% to 29% of femoral veins through which balloon valvuloplasty has been performed were noted to be occluded at follow-up. In the present series, 3 out of 36 patients (8%) whom we restudied following pulmonary valvuloplasty had blocked femoral vein. It is the consensus that the femoral venous occlusion is more common in small infants. Data with regard to the incidence of femoral artery occlusion at follow-up are not readily available from the literature. Of the 23 infants and children who underwent follow-up catheterization after balloon coarctation angioplasty from our study, 3 femoral arteries were found to be obstructed (complete in 2 and partial in 1); however, all of them had good collateral flow.

Aneurysms at the site of balloon dilatation of aortic coarctation were reported in both native and postoperative coarctations; 8% to 55% incidence was noted by these workers. These patients with aneurysm did not require therapy and did not have any ruptured aneurysm. We restudied 20 children, 6 to 30 months, following dilatation of native coarctations and 3 children, 6 to 22 months, following dilatation of recoarctation; none developed aneurysms. The reason for this difference is not clear.

Doppler evidence for pulmonary insufficiency appears sensitive but was studied by only a few investigators. Rocchini and Beekman reported pulmonary insufficiency in 31 out of 37 (84%) patients, while Robertson et al found mild pulmonary insufficiency in all 29 patients studied. In our group, 34 out of 43 (79%) patients had Doppler demonstrable pulmonary insufficiency. However, the pulmonary insufficiency was minimal, as evidenced by lack of right venoatrial volume overloading (normal sized right ventricle and no paradoxical septal motion) in this group of patients as well as by equilibrium gated radionuclide angiograms reported by Tynan. Although, the longer-term follow-up studies should be scrutinized for progressive right ventricular volume overload, the current data suggest that the pulmonary insufficiency produced by balloon valvuloplasty is unlikely to be problematic.

There are very few studies reporting intermediate- or long-term results and much fewer studies investigating recurrence following balloon dilatation. The available information with regard to pulmonary stenosis and aortic coarctation will be reviewed.

Recurrence of valve stenosis following balloon pulmonary valvuloplasty has been reported but the reasons for the restenosis at intermediate-term follow-up has been studied only to a limited degree. We have systematically investigated the cause of recurrence of pulmonary stenosis following balloon valvuloplasty. Sixty-three children, on the basis of results of 6 to 34 month follow-up catheterization data, were divided into group 1 with good results (29 children with pulmonary valve gradients of 30 mm Hg or less) and group 2 with poor results (7 children with gradients greater than 30 mm Hg). Fourteen demographic, anatomic, physiologic, and technical factors were examined by multivariate logistic regression analysis to identify factors associated with restenosis. These risk factors were: (1) residual pulmonary valve gradient in excess of 30 mm Hg, immediately following balloon valvuloplasty and (2) balloon to pulmonary valve annulus ratio of 1.2 or less. Dysplastic pulmonary valves did not seem to play a role in recurrence, and this may have been due to the use of large balloons with dysplastic valves. The data suggested that balloon/annulus ratio of 1.2 or less is the cause for pulmonary valve restenosis at intermediate-term follow-up, and such recurrences can be predicted in patients with immediate postvalvuloplasty pulmonary valve gradient in excess of 30 mm Hg.

Recoarctation following balloon angioplasty has been reported but the reason for recurrence at intermediate-term follow-up has been studied only to a limited degree.41 We have investigated causes of recoarctation following bal
loon angioplasty of aortic coarctation. Twenty children, on the basis of results of 6 to 30 month follow-up catheterization data, were divided into group A with good results (13 patients with gradients ≤ 20 mm Hg and no recoarctation on angiograms) and group B with fair and poor results (7 patients with gradients > 20 mm Hg with or without recoarctation on angiography). None of the patients developed aneurysms. Thirty demographic, anatomic, physiologic, and technical variables were examined by multivariate logistic regression analysis and four factors were identified as risk factors for developing recoarctation: (1) age less than 12 months, (2) aortic isthmus less than half the size of ascending aorta, (3) coarcted aortic segment smaller than 3.5 mm prior to dilatation, and (4) coarcted aortic segment less than 6 mm after angioplasty. Predilatation systolic pressure gradient, across the aortic coarctation, in excess of 50 mm Hg previously implicated as a cause of recurrence and the ratio of balloon to coarcted aortic segment or descending aortic diameter were carefully scrutinized but did not seem to influence the recoarctation. The identification of risk factors may help in the selection of patients for balloon angioplasty. Avoiding or minimizing the number of risk factors may help reduce the chance of recoarctation following angioplasty.

Conclusions and Future Directions

The technique of balloon dilatation of stenotic lesions of the heart and great vessels in infants and children has been available since 1982. This technique has been used extensively in isolated valvar pulmonic stenosis with excellent immediate and reasonably good intermediate-term follow-up results. Refinements in the technique may further decrease the restenosis rate. Balloon pulmonary valvuloplasty is now the procedure of choice in the treatment of moderate to severe valvar pulmonic stenosis. Although good immediate and intermediate-term follow-up results of balloon angioplasty of aortic coarctation have been reported, recommendations for use of this technique as a choice treatment have been clouded by the reports of development of aneurysms at the site of coarctation dilatation. We feel that balloon coarctation angioplasty is the treatment of choice in neonates and small infants while general use of this technique in both native and postoperative coarctations in older children should await longer follow-up results of larger number of children.

Balloon dilatation of aortic valve stenosis and branch pulmonary artery stenosis produced reasonable immediate results but long-term results are needed prior to making definitive recommendations. However, this technique is attractive in neonates with critical aortic obstruction. Balloon valvuloplasty of pulmonary stenosis in association with other congenital heart defects (although reported by only two groups of workers), the good immediate and follow-up results lead me to recommend it as an effective alternative to surgical aorta-to-pulmonary anastomosis. Despite good results in many other lesions, there is very little experience in children who have each of these defects to make a definitive recommendation. Thus far, only one- to two-year follow-up results are available. Five- to ten-year follow-up results to document long-term effectiveness of balloon dilation are needed for all stenotic lesions.

Miniaturization of currently bulky dilating catheter systems and improvement of rapidity of inflation/deflation of balloons are necessary for increasing the safety and effectiveness of this technique in infants and children. Meticulous attention to the details of technique and further refinement of the procedure will further reduce the complication rate. For vascular lesions with poor results from balloon angioplasty (peripheral pulmonary artery or pulmonary vein stenosis), intravascular stents (which are currently being tested in animal models and humans) may prove valuable to keep the stenotic lesions open. The transcatheter laser technique to relieve stenotic lesions and the visualization of these lesions, while relieving the obstruction with a dual fiberoptic catheter, have been used in postmortem stenotic lesions and animal models. Further development and refinement of these techniques in animal models, followed by clinical trials, are necessary prior to their application in infants and children with obstructive lesions in the heart and great vessels. The transcatheter techniques offer promise as excellent alternatives to open or closed heart surgery in the treatment of several congenital heart defects.
Acknowledgment

Supported in part by a grant from Oscar Rennebohm Foundation, Inc., Madison, Wisconsin, USA.

References


VALVULOPLASTY AND ANGIOPLASTY

1 Am Coll Cardiol 1987;10:1078-84.