Catheter balloon valvuloplasty of aortic and mitral stenosis in adults: 1987

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THERAPEUTIC catheter intervention probably started with Dotter and Judkins performance of transluminal treatment of arteriosclerotic obstruction of peripheral vessels. Rashkind extended the therapeutic use of the catheter to intracardiac work with the performance of balloon atrial septostomy for transposition of the great arteries. Over the next 20 years, the field has blossomed, with removal of fragments of other catheters and intravenous lines that had become accidentally sheered off and left in the right heart or pulmonary artery; closure of atrial septal defect and patent ductus arteriosus, blockage of vena cava for prevention of recurrent pulmonary emboli and fragmentation of massive pulmonary emboli, closure of arterial and venous malformations with the use of coils, glues, and other substances; dilatation of systemic and pulmonary arterial and venous stenoses, of coarctation of the aorta, and of coronary arteries and bypass grafts; intracoronary thrombolysis; and ablation of conducting and accessory tissues and of tachyarrhythmias (table 1). It was natural that an attempt should be made to dilate stenotic cardiac valves. The technique is best called catheter balloon valvuloplasty (CBV) because the catheter may be introduced by cutdown; valvotomy and commissurotomy have been used to describe surgical dilatation of stenotic valves for over three decades and balloon dilatation of coronary arteries is called angioplasty.

A variety of balloon catheters (single, double, and trefoil) have been used. This is a rapidly evolving technology and many changes are likely to occur that can be expected to improve and fine tune the results that are obtained and, at the same time, reduce the complications and risks.

CBV for pulmonary valve stenosis. CBV for pulmonary valve stenosis with the single-balloon technique was used by Kan, Pepine, and Lababidi and their colleagues, the double-balloon technique has been used by Ali Khan et al., and the trefoil technique was described by Meier et al. These techniques produced major, and at times dramatic, reductions in the pulmonary valve gradients and right ventricular systolic pressures, while heart rate, cardiac output, and systemic arterial pressure showed no significant change. Therefore, CBV is the initial procedure of choice in the treatment of patients with severe, and also moderate, pulmonary valve stenosis.

The results obtained with pulmonary valve stenosis showed it to be safe and effective; this led the Food and Drug Administration to approve the clinical use of the balloon catheter for dilatation of pulmonary valve stenosis.

Other considerations. There are a number of dangers facing cardiology and medicine, one of which is the appearance of potential conflicts of interest. Patton suggests it is time we in cardiology separate the doers from the thinkers. These concerns will also apply to CBV, and at this time include issues of self-referral of patients, of perceived indications for interventional therapy, and of contraindications to standard therapy. The ideal way of dealing with our various problems is uncertain; nevertheless, performance of CBV in a responsible manner, including obtaining consent after the patient is fully and adequately informed and meticulous reporting of all the findings and complications of CBV, can only be helpful.
TABLE 1
Therapeutic catheter interventions

| Transluminal treatment of arterial obstruction |
| Balloon atrial septostomy |
| Removal of catheter fragments |
| Closure of ASD and PDA |
| Blockage of IVC for recurrent PE |
| Fragmentation of massive PE |
| Closure of arterial and venous malformations |
| Balloon dilatation of obstruction in: |
  | Systemic arteries |
  | Pulmonary arteries |
  | Pulmonary veins |
  | Aorta (coarctation) |
  | Coronary arteries |
  | Coronary bypass grafts |
| Intracoronary thrombolysis |
| Catheter ablation of: |
  | Conducting tissues |
  | Accessory pathways |
  | Tachyarrhythmias |
| Catheter balloon valvuloplasty |
| Valve stenosis (pulmonary, aortic, mitral, and tricuspid) |
| Bioprosthetic stenosis |

ASD = atrial septal defect; PDA = patent ductus arteriosus; IVC = inferior vena cava; PE = pulmonary embolism

Routine clinical use of a cardiovascular device in the United States requires prior approval of the device for the intended use by the Food and Drug Administration under the prevailing law of this country. Therefore, use of these catheters for CBV of stenotic cardiac valves other than the pulmonary valve must be considered investigational at the present time.

CBV for aortic valve stenosis. CBV for aortic valve stenosis was reported by Lababidi et al. in children and adolescents and by Cribier et al. in adults. The increase in valve area in the young is a result of commissural splitting and stretching of valve tissue, and in adults with calcified valves it results from commissural separation, fracture of the calcified leaflet, and displacement and stretching of rigid valve cusps.

For any size of stenotic aortic valve, the systolic gradient across the valve is determined by the stroke volume and systolic ejection period, both of which are dependent on the loading conditions of the left ventricle, resistance in the arterial system, and the contractile state of the left ventricle. Thus, it is important to obtain complete data on hemodynamic and ventricular function and also to carefully determine and calculate aortic valve areas, rather than just the systolic gradients and cardiac outputs, before and after CBV.

The reported average aortic valve areas after CBV have ranged from 0.5 to 1.1 cm\(^2\). Two of the larger series of patients reported aortic valve areas after CBV that averaged 0.8 cm\(^2\) and 0.9 cm\(^2\), only about one-third of patients have aortic valve areas of 1.0 cm\(^2\) or more after CBV. Many of the reported aortic valve areas after CBV are in the range that has traditionally been considered to represent severe aortic stenosis, and therefore, a need to recommend valve replacement. Moreover, valve areas after CBV are very much smaller than those achieved with use of aortic valve replacement devices.

If patients still have severe to moderate aortic valve obstruction after CBV, then the following four questions require answers: (1) Why do some patients have “large” reductions of gradient across the valve? (2) Why are many patients symptomatically improved?

Answers to these two questions become apparent when one examines the relationship of gradient to valve area at a fixed rate of flow. Usually, no outflow gradient can be demonstrated across narrowed aortic valves until the effective orifice size is reduced to less than 40% to 60% of the normal valve area. A similar phenomenon also occurs with stenosed arteries. It is therefore possible to have a stenotic valve and no demonstrable gradient. Once the gradient appears, the relationship of gradient to valve area is curvilinear; therefore, the gradient rises precipitously when the effective orifice size of the valve is critically reduced to less than 35% of normal. As a result, small increases in valve area of very critically narrowed valves will result in significant reductions of gradient. Thus, it is possible to increase the valve area of a severely narrowed valve only a little and still bring about a reduction of gradient that appears at first glance to be “large.” The small increase in valve area will alter the loading condition of the ventricle, which could be sufficient to improve the hemodynamics and symptomatic status of certain selected patients, such as those in whom the aortic stenosis has resulted in severe impairment of left ventricular function. The pitfalls of the accurate assessment by subjective means of the symptomatic improvement of patients, particularly when evaluating new therapies, are well known; therefore, objective documentation of this improvement is essential.

(3) What are the advantages and disadvantages of this modest improvement in valve area?

An advantage of this modest increase in valve area after CBV is that there is little or no increase in or production of new severe aortic regurgitation. It should be recalled that in the early stages of valve surgery, surgical aortic valvotomy in adults with rigid
calcified valves usually resulted in much larger orifice sizes than those achieved with CBV, but the results were usually not good, probably because they also produced unacceptably large amounts of aortic regurgitation. A clear disadvantage is that this degree of aortic stenosis is known to be associated with a very poor prognosis and has been considered an indication for valve replacement.

(4) Are there any “long-term” implications?

At the present time, the long-term results of CBV for aortic stenosis are unknown. Since valve areas obtained after valve replacement are much larger, the implication is that the demonstrated favorable effects of valve replacement on symptomatic status, hemodynamics, left ventricular function, and survival may not be obtained after CBV. For example, in patients with reduced left ventricular ejection fraction before CBV, the increase noted after CBV has been small: in one study the ejection fraction increased from an average of 0.38 to 0.45 and in another study approximately one-half of the patients showed no change or an actual reduction in ejection fraction. On the other hand, after valve replacement in patients with clinical heart failure, left ventricular ejection fraction has been shown to increase from an average of 0.34 to 0.63 and to normalize in two-thirds of the patients. Moreover, it was noted in one study to increase in all but one patient who had suffered a perioperative myocardial infarction. After aortic valve replacement, the demonstrated 5, 10, and 15 year survivals of patients was greater than or equal to 75%, 56%, and 45%, respectively. After aortic valve replacement for severe aortic stenosis, the 12 year survival of patients aged 60 years old or older was 56% or greater, and the 7 year survival of patients in congestive heart failure with reduced left ventricular ejection fraction was 67% (85% in the operative survivors). It seems possible that CBV will not match these results unless the valve areas achieved after CBV improve significantly without producing increased aortic regurgitation. Follow-up data from the first few months after CBV have indicated continued mortality, and one likely cause of this is unrelied severe aortic stenosis.

CBV for mitral valve stenosis. CBV for mitral valve stenosis was reported by Inoue et al. in March 1984 and for children and adolescents by Lock et al. in December 1985. In April 1986, Al Zaibag et al. reported the use of the double-balloon catheter technique. CBV increases area of the mitral valve by producing commissural separation without injury to valve leaflets or chordae, as first reported under direct vision by Inoue et al. This finding has subsequently been confirmed with use of two-dimensional echocardiography.

The reported average mitral valve area after CBV with use of the single-balloon technique is 1.4 cm² or less, whereas, with use of the double-balloon technique, the average mitral valve area is 2 cm² or more. Results obtained with a single balloon, modified single balloon, and the double balloon are very different; thus, it is important that results with the different techniques be presented separately. With use of the double-balloon technique, the mitral valve areas achieved are greater if the balloon sizes used are matched to the pre-CBV mitral annular diameter determined by two-dimensional echocardiography.

During balloon inflation across the stenotic mitral valve, systemic arterial pressure falls rapidly and pulmonary arterial wedge pressure increases. In many patients with aortic stenosis, systemic arterial pressure also falls markedly and returns slowly to baseline values after balloon deflation. After balloon deflation, it is important that the heart fill rapidly to allow systemic flow to return toward an acceptable range as soon as possible. Therefore, hypovolemia has to be avoided, as must excess volume loading.

Successful CBV results in an immediate reduction in left atrial pressure and increases in cardiac output and mitral valve area, pulmonary arterial pressure and calculated pulmonary vascular resistance fall to a lower steady state in 6 to 24 hr. Virtually identical findings were reported by the Mayo Clinic Group in 1954 after successful surgical mitral commissurotomy. Mitral valve areas after double-balloon CBV are similar to those previously reported after surgical mitral commissurotomy or valvotomy and mitral valve replacement, which makes this an acceptable technique from a hemodynamic point of view.

Restenosis is very common after surgical finger valvotomy. Within 3 to 6 months of CBV, some degree of restenosis occurs even after double-balloon valvuloplasty; however, it is uncertain at this time whether this is partly a methodologic problem. Long-term results after CBV for mitral stenosis are unknown at the present time. Surgical closed mitral commissurotomy improves the survival of patients with mitral stenosis who are in functional class II and also that of those who are in functional classes III and IV. Twenty-four year follow-up of 3742 patients who underwent closed mitral valvotomy in Vellore, India, from 1956 to 1980 were reported by John et al. The 24 year survival was 84%; the thromboembolism and restenosis rates ranged from 0.03% to 0.16% per year and 0.42% to 1.14% per year, respectively. Results of closed mitral
valvotomy reported from this country are much less spectacular.64,75 Results of valvular operative procedures are significantly dependent on patient-related factors,76 and it is therefore important that results of CBV in patients from different countries be reported separately. National registry data will be very valuable in providing an overview of the results,30 but experience from individual centers should also be presented separately.30 Moreover, it is very important that pre-CBV patient characteristics be reported in detail and that results in patients with different characteristics be presented separately. Results from this country after open mitral commissurotomy show a low operative mortality (0 to 1%), small late mortality (≤ 5% at 10 years), and low thromboembolism rates (≤ 2% per year); however, restenosis is a continuing problem.77-81 It remains to be seen whether findings of CBV will match these surgical results.

Complications of CBV. A large number of potential complications may occur after CBV (table 2); this expectation is based on a personal three-decade experience with cardiac catheterization and angiography, and on knowledge of the literature and of CBV.22-25,28-30,61-68,82 Many of these complications have already been documented and their frequency of occurrence is of interest. Some of the complications are very serious. Over time, it will be important to prevent or reduce their incidence.

In-hospital mortality associated with CBV of calcified aortic valve stenosis has been reported in 5% to 7.6% of patients,28,30; that of patients undergoing CBV for mitral stenosis is 4%.83 It is too early to begin to discuss “late” mortality. Acute myocardial infarction, systemic embolism, and cardiac perforation with tamponade have been reported in a small number of patients.28,30 In one series, five of 23 patients (22%) undergoing CBV for mitral stenosis developed a left-to-right shunt at the atrial level, and in two of these five, the pulmonary-to-systemic flow ratios were 1.8 and 2.3 to 1.67 These flow ratios are generally considered an indication for closure of congenital secundum atrial septal defects.84 Some patients have developed severe valve regurgitation.64,67 Perforation, tear, and avulsion of the diseased valve have been reported,24 and even more disconcerting is the fact that these same injuries have been caused to other normal (that is, uninvolved) valves. Restenosis has been noted, particularly with CBV for mitral stenosis.65,68 Arrhythmias and vascular complications will occur, and it should be recognized that even blood transfusions are not without risk.

On the other hand, it must be remembered that valve replacement is also a palliative procedure that is associated with long-term mortality and morbidity;22,49-59; therefore, the search for an ideal valve replacement device88 and other forms of treatment must continue.

Indications for CBV. Since CBV is in its early stages of development, definitive indications for its use cannot be given at the present time. Suggested guidelines for its use in adults are as follows. The stenosis should be severe, the usual indication for intervention should be present, and the patient should not be in need of other forms of cardiac surgery, such as other valve disease or coronary artery disease. Patients in whom surgery is not possible for noncardiac reasons, in whom the risks of surgical treatment are considered to be very high, or who refuse surgery may be the best candidates for CBV, particularly if they have aortic stenosis, which is frequently not adequately relieved by CBV. CBV may be the initial procedure of choice in selected patients and in experienced centers. Three examples can be cited: (1) the patient with severe val-

### TABLE 2

<table>
<thead>
<tr>
<th>Complications of catheter balloon valvuloplasty (reported or possible)</th>
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<tbody>
<tr>
<td>Death (early and “late”)</td>
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<tr>
<td>Acute myocardial infarction</td>
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<tr>
<td>Embolism (systemic and pulmonary)</td>
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<td>Cardiac perforation (left ventricle, aorta, left atrium, right atrium)</td>
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<td>Cardiac tamponade</td>
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<td>Left-to-right shunt (at atrial level)</td>
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<td>Valve related</td>
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<td>Valve regurgitation</td>
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<td>Perforation, tear, and avulsion of diseased valve cusp and chordae tendineae</td>
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<tr>
<td>Perforation, tear, and avulsion of normal valve</td>
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<tr>
<td>Inadequate result</td>
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<tr>
<td>Unsuccessful</td>
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<tr>
<td>Restenosis</td>
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<tr>
<td>Infection (endocarditis; catheter entry site)</td>
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<td>Arrhythmias</td>
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<td>Ventricular tachycardia/ventricular fibrillation</td>
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<td>Atrial arrhythmias</td>
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<td>Bradycardias</td>
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<td>Conduction abnormalities</td>
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<td>Vascular</td>
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<td>Blood loss and hemorrhage</td>
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<td>Arterial thrombosis</td>
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<tr>
<td>Arteriovenous fistula</td>
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<tr>
<td>Arterial pseudoaneurysm</td>
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<tr>
<td>Other damage to vessels</td>
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<tr>
<td>Vasovagal episodes</td>
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<td>Blood transfusion</td>
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<td>Hypotension</td>
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<td>Angina</td>
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<td>Balloon rupture</td>
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<tr>
<td>Others</td>
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vular stenosis who needs a noncardiac surgical procedure urgently, such as removal of a suspected carcinoma, abdominal surgery for an infected gall bladder, or subacute intestinal obstruction, (2) the patient with severe aortic stenosis who has severe symptomatic left ventricular dysfunction in whom modest relief of the stenosis may make the patient a better candidate for surgery, and (3) the patient with a pliable mitral valve in whom a good result is likely, particularly when the double-balloon or other similar technique will be used.

For clinical investigations, the above indications for CBV should be appropriately modified.

Other treatment. Antibiotic prophylaxis for prevention of infective endocarditis and of recurrence of rheumatic carditis, if appropriate, is an integral part of the clinical management of these patients. It needs to be recognized that CBV is a palliative procedure. Continued clinical management is important; these patients need close follow-up and appropriate treatment, which may include valve surgery.

Summary and conclusions. CBV for adults with aortic and mitral stenosis is investigational at the present time and should usually be performed within the guidelines of clinical investigation. The technology is an evolving one with regard to (1) types of catheters and balloons, (2) methods of catheter insertion and placement, and (3) patients and valves that are suitable for and will respond well to CBV. The initial results range from disappointing to excellent and must be kept in perspective. The procedure is clearly a palliative one; ideal results are not being achieved at present. Some of the complications are very serious. Nevertheless, CBV is a most promising catheter interventional technique for patients with valvular heart disease. Proper selection of patients and complete reporting of results is important.

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