The year 1977 has come to represent a watershed year in clinical cardiology because of the manner in which Gruentzig's initial description of percutaneous coronary transluminal angioplasty forever changed the management of coronary heart disease. It is likely that the year 1986 will come to be similarly regarded for the manner in which reports of successful percutaneous balloon valvuloplasty in patients with calcific aortic stenosis promise to revise the management of valvular heart disease.

The application of balloon valvuloplasty to adult patients with aortic stenosis represents the latest in a series of collaborative cycles between pediatric and adult cardiologists in the development of interventional catheter technology. Rashkind and Miller introduced the interventional catheter into clinical cardiology as a palliative therapy for infants with transposition of the great vessels. Gruentzig's efforts extended the domain of therapeutic catheterization to the adult population. Kan et al then retook the mantle and established the feasibility of balloon dilation for the treatment of pulmonic stenosis in children, soon thereafter extended to a variety of congenital cardiac defects, including congenital aortic stenosis.

PRELIMINARY RESULTS

The year 1986 has seen the mantle pass once more to the adult catheterization laboratory. Following upon the pediatric experience with percutaneous valvuloplasty for stenotic but noncalcified aortic valves, Cri-bier et al used a 3-cm-long balloon, originally designed for percutaneous pulmonary valvuloplasty, to perform percutaneous aortic valvuloplasty. In three patients, 68, 77, and 79 years old with heavily calcified aortic valves, peak gradients fell from 90 to 40, 80 to 30, and 60 to 30 mm Hg. In the latter two patients, aortic valve area improved from 0.4 to 0.6 and 0.5 to 0.7 cm². Subsequently, McKay et al reported the first application of the technique in this country in two patients, 93 and 85 years old: peak gradients diminished from 66 to 32 and 44 to 31 mm Hg, respectively, while calculated orifice area increased from 0.4 to 0.6 and 0.5 to 0.7 cm². Preliminary experience with this technique at our institution has paralleled that described in these initial reports: among 24 patients undergoing balloon valvuloplasty between May and December, 1986, peak aortic valve gradient fell from an average of 68 ± 8 mm Hg, postvalvuloplasty. Likewise, aortic valve area increased from 0.42 ± 0.04 to 0.81 ± 0.06 cm² postvalvuloplasty. A cumulative total of over 400 additional patients recently reported in abstract form has convincingly demonstrated the potential utility of this technique in the adult age group.

TECHNICAL LIMITATIONS

Despite these dramatic early results, however, the technology for performing aortic valvuloplasty is not yet mature; accordingly, several caveats deserve specific comment. From a technical standpoint, the most serious liability of the procedure is the fact that currently available balloon sizes, only the 15-cm diameter balloon can be accommodated by a 12 Fr sheath for percutaneous insertion. Although a 14 Fr sheath is commercially available, initial experience with this sheath, including our own, has disclosed that it may be excessively traumatic, particularly in older, tortuous, atherosclerotic, calcified peripheral arteries. Because a 15-cm diameter balloon alone is seldom adequate to accomplish an optimal hemodynamic result, the 12 Fr sheath must thus be removed prior to wire-guided, percutaneous insertion of larger balloons. As a result, the incidence of serious vascular complications, including arteriovenous fistulae, pseudoaneurysm formation, and serious groin hemorrhage, has been reported to be as high as 12 percent. While the transseptal technique constitutes an alternative to the percutaneous arterial approach, the use of larger balloon catheters may result in a residual shunt through the atrial septostomy.
NONPERCUTANEOUS APPROACH

As a result of these considerations, we have preferred to perform balloon insertion via a limited cutdown over the common femoral artery. This approach has several advantages. First, it eliminates any possibility of mistaken insertion of the balloon into the superficial femoral artery in the elderly patient in whom the inguinal crease may be an unreliable landmark for arterial puncture due to loss of cutaneous elasticity with or without a large pannus of adipose tissue. Second, among our first 24 patients in whom we employed this approach, our transfusion requirements due to direct manual control of hemorrhage through the arterial puncture during balloon exchanges has reduced transfusion requirements in these patients below what has been previously described by others. Third, in this same group of patients, we have had no traumatic vascular complications. Fourth, the requirement for protracted, percutaneous blind manual tamponade at the conclusion of the procedure is eliminated.

A fourth advantage of operatively-guided insertion is that it does not limit the level of anticoagulation that may be required for the procedure. In this regard, it is worth noting that the incidence of (presumably embolic) cerebrovascular accidents observed to date by the French registry has been 2 percent (eight patients). We, too, have had one procedure complicated by a focal, apparently embolic brain stem infarct. While the possibility exists that these complications may be related to peripheral release of debris from the valve, the potential thrombogenic surfaces of the catheters and wires used in the procedure represent an alternative source of peripheral emboli. As a result, we have employed a generous dose of heparin, similar to that used for coronary angioplasty. Because wound closure is performed in an operative manner, the heparin dose need not be limited, and prophylaxis against embolic complications is thus optimized.

While attempts are currently being made to obviate many of the above issues by fabricating balloon catheters that can be accommodated by a 12-or-less Fr sheath, questions persist regarding the remaining dimensions of the balloon. Because the 3-cm-long balloon tends to prolapse antegrade or retrograde across the valve at maximal balloon inflation, most investigators have concluded that a longer balloon length is required. Precisely how long the balloon should be is currently a matter of controversy: 4 cm has the advantage of being easily accommodated by even the most cavity-obliterated, hypertrophied left ventricle without risk of apical perforation, while 5 to 6 cm may compensate better for to-and-fro movement during balloon inflation.

Alternative balloon designs, such as three small balloons arranged around a central catheter shaft, are also under investigation. Although a more protracted inflation is a potential advantage of the latter design, the data to support this assertion—or for that matter, any data indicating the optimal duration of balloon inflation—are not available.

DOUBLE BALLOON TECHNIQUE

In our laboratory, we have used a double balloon technique in cases where use of larger-diameter balloons failed to yield an adequate hemodynamic result (Fig I). While this approach has been useful in selected patients, the ultimate role of the two-balloon technique for aortic valvuloplasty requires more thorough investigation.

![Graph](http://journal.publications.chestnet.org/pdfaccess.ashx?url=/data/journals/chest/21565/)

**Figure I.** Hemodynamic results in a patient in whom calculated aortic valve area (AVA) increased from only 0.5 to 0.7 cm² following serial, single balloon (up to 25 mm) dilation. Use of double balloon (15 and 18 mm) technique further increased AVA. Ao is aorta; CO, cardiac output; and LV, left ventricle.
FUTURE CONSIDERATIONS

The issue that has raised the greatest concern regarding aortic valvuloplasty is a biologic rather than technical one: namely, the subsequent clinical course of patients in whom a significant, if not "critical," gradient persists postvalvuloplasty. On the one hand, results obtained using balloon valvuloplasty in many patients compare favorably with those obtained in many patients with prosthetic aortic valves. Among 34 patients studied by Henry et al\textsuperscript{a} six months after aortic valve replacement, for example, aortic valve orifice area calculated by the Gorlin formula was 1.05 ± 0.31 cm\textsuperscript{2}. Intraoperative studies of patients following Carpentier-Edwards valve replacement likewise disclosed a mean residual orifice area of 1.1 ± 0.40 for patients with size 19 prosthesis and 1.4 ± 0.60 cm\textsuperscript{2} in those with a size 21 prosthesis.

On the other hand, whether even a 100 percent increase in aortic valve area and a 50 percent reduction in aortic valve gradient will be sufficient to protect against the risk of sudden death\textsuperscript{10} when the postvalvuloplasty aortic valve area is less than 1.0 cm\textsuperscript{2} has not yet been answered. The answer to this question raises a more basic question regarding which individuals represent appropriate candidates for the procedure. In a relatively elderly patient with multiple medical problems that make cardiac surgery an unrealistic consideration, the threshold for tolerating a significant residual gradient will be lower than in a younger, more active person.

The unknown incidence of restenosis constitutes a second aspect of concern regarding the long-term efficacy of aortic valvuloplasty. No serial hemodynamic studies have been reported to date to address this issue. This concern is amplified by uncertainty regarding the mechanism by which balloon dilation affects hemodynamic improvement. When commissural fusion complicates calcific aortic stenosis (Fig 2), there exists a potential basis for hemodynamic improvement analogous to that observed in balloon-induced commissural splitting of stenotic mitral valves.\textsuperscript{11} Unfortunately, commissural fusion is an uncommon feature of calcific aortic stenosis involving a congenitally normal three-cuspid aortic valve,\textsuperscript{12} the most common anatomic basis for aortic stenosis in patients over age 65.\textsuperscript{13} Although Mckay et al,\textsuperscript{8} Vahanian et al,\textsuperscript{14} and we have observed leaflet fractures in formalin-fixed postmortem specimens, no such leaflet fractures were reported during intraoperative aortic balloon dilation\textsuperscript{5} or in the one fresh, unfixed postmortem specimen that we have dilated. Furthermore, whatever mechanism explains the success of balloon aortic valvuloplasty, it may not apply to calcified, congenitally bicuspid aortic valves. Among our initial 24 patients, balloon dilation failed to improve orifice area in three, and did not obviate recurrent symptoms of severe paroxysmal dyspnea in a fourth. At surgery (three patients) or necropsy (one), all were found to have a calcified congenitally bicuspid aortic valve.

Despite the fact that important questions remain to be answered, balloon valvuloplasty seems likely to become standard therapy for patients with critical aortic stenosis who either refuse surgery or are judged...
to be poor operative candidates. Technical improvements in catheter and balloon design, as well as the outcome of clinical investigations now underway, will determine the extent to which this procedure should be more widely applied.

References