Editorial Comment

Severe Aortic Stenosis in the Sick Octogenarian
A Clear Indicator for Balloon Valvuloplasty as the Initial Procedure

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The introduction of balloon valvuloplasty for aortic stenosis first reported by Cribier and colleagues in 1986 was initially greeted with enthusiasm, especially by the interventional cardiologists who had in Samson-like tradition crushed the pillars of atherosclerotic coronary arteries with balloon catheters and were now anxious to do the same to calcified aortic valve leaflets. The success of a similar procedure for pulmonic valvular stenosis was a further spur.

The procedure can be done with low periprocedure mortality and morbidity and evidence of some substantial increase in valve area, especially if presented as percentage increase over initial valve area, and marked relief of symptoms. For instance, Letac and colleagues report 218 patients with aortic stenosis in whom the peak-to-peak aortic valve gradient changed from 72±25 to 29±14 mm Hg and the calculated aortic valve area changed from 0.52±0.18 to 0.93±0.33 cm². In 69 patients (32%), the achieved aortic valve areas was 1.0 cm² or more. Similar results have been accomplished by others. In these patients, symptoms have been considerably relieved—87% were in New York Heart Association (NYHA) functional classification III or IV before valvuloplasty and only 14% were in this functional class after valvuloplasty.

Unfortunately, with even short-term follow-up of these patients, mortality was high, and with restudy by catheterization or echocardiographic-Doppler techniques, the fear that restenosis, the Delilah of the Samson procedure, would occur was confirmed. In a mean of 8 months of follow-up by Cribier and colleagues of their first 148 patients, 24 (16%) died. Safian and colleagues reported 170 patients with a mean age of 77.5±5 years in whom aortic valve area increased from 0.6±0.2 to 0.9±0.3 cm². In a follow-up of 9.1 months, 25 patients died (14.7% mortality), and survival at 1 year was estimated at 74%.

Follow-up has shown a distressing return of symptoms and, when measured, evidence of restenosis. In Cribier and colleagues’ study, 41 patients had routine recatheterization, and 10 of these patients (25%) had restenosis as defined by a 50% loss of postvalvuloplasty gain in aortic valve area. If this is combined with early and late mortality, 41% showed evidence of poor results. In Safian and colleagues’ study of 171 patients followed for a mean of 9.1 months, symptoms recurred in 44 (25.9%), and mortality at 1 year was 26%. Combining late deaths and recurrent symptomatology, a restenosis incidence of 44% was postulated.

Both of these groups, as well as others, have concluded that balloon aortic valvuloplasty for aortic stenosis is a palliative procedure, and its place is best limited to patients who are not operative candidates for any reason or who have such profound congestive heart failure that their surgical mortality is believed to be prohibitive, that is, a means of improving the patient’s status temporarily so that aortic valve replacement can be performed at a lower risk.

In an attempt to find the proper indications for balloon valvuloplasty as the initial procedure, the problem of aortic stenosis in the very elderly patient has been examined. These patients, especially those more than 75 or 80 years old, are known to be at higher risk for aortic valve replacement. Figures of 25–33% mortality have been advanced in those 75 years old or older, although there are two few studies with sufficient numbers of patients to be certain. A recent, frequently cited study by Edmunds

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and colleagues reviewed 100 patients who were 80 years old or older with open heart surgery, 50 patients with aortic valve disease, and 41 with coronary artery disease as their primary indica-

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tions. Ninety percent had NYHA class IV symptomatology. The 90-day mortality was 29%, and an additional 17 died 2–104 months after discharge. The 90-day mortality for aortic stenosis was similar to the overall mortality. However, not all perioperative mortality in the elderly has been this high. Craver and colleagues\textsuperscript{13} retrospectively studied 1,148 patients operated on for aortic stenosis who had an overall perioperative mortality of 4.2%. Mortality was 7.3% for patients older than 70 years old and 2.5% for patients less than 70 years old. Operative mortality was 12.5% for patients older than 80 years old. The survival in 196 patients more than 70 years old was 83% at 1 year and 52% at 5 years.

The operative mortality in all elderly patients with severe aortic stenosis is not known because all studies of patients operated on for aortic stenosis have been in selected patients without overwhelming contraindications to surgery and have eliminated the patients who are likely to have the highest mortality. The overall low mortality and good survival of patients with aortic valve replacement less than 80 years old is the major reason that balloon valvuloplasty does not appear to be an alternative for the patient with aortic stenosis who is an operative candidate. For the same reasons, for patients who are more than 80 years old and have severe symptomatic aortic stenosis and other medical conditions such as respiratory failure, severe congestive heart failure, or renal or hepatic dysfunction, which would make them poor operative candidates, an alternative procedure is desirable and needed.

From the group who pioneered balloon valvuloplasty in aortic stenosis, in this issue of Circulation Letac and colleagues\textsuperscript{14} present the results of balloon valvuloplasty in 92 consecutive patients 80 years old or older (mean age, 84±3.7 years) in whom balloon valvuloplasty was the initial procedure. These patients were extremely symptomatic; 86% were in NYHA class III or IV, and the rest had severe angina, syncope, or both. Being unselected, including 20% who had some other associated pathologic situation that made them unacceptable as surgical candidates, these patients probably faithfully represent the old patient in severe congestive heart failure with severe aortic stenosis that is now increasingly being found by echocardiographic-Doppler techniques, in whom the operative mortality is likely to be very high and who at present is usually not offered surgery. The periprocedure mortality in this group was 6.5% with a low complication rate of one stroke, one requirement for temporary pacemaker, and 14 patients (15%) who had a hematoma or thrombus in the femoral puncture site. The aortic valves were extremely stenotic, and response to valvuloplasty was excellent. The pre-valvuloplasty peak-to-peak transaortic valve gradient was 71±27 mm Hg, which dropped to 27±15 mm Hg postprocedure. The aortic valve area rose from 0.48±0.16 before to 0.91±0.35 cm\textsuperscript{2} after balloon valvuloplasty.\textsuperscript{14}

The symptomatology in aortic stenosis in large part is related to the effect of increased afterload on the left ventricular muscle and compromise of the myocardial oxygen demand-supply relation. With a marked drop in gradient after valvuloplasty, there is a marked decrease in afterload, which, together with no change or an increase in cardiac output, can only improve myocardial perfusion in relation to myocardial oxygen demand and result in alleviation of symptoms. This would also be true in very symptomatic patients who had very tight aortic stenosis with valve areas of 0.4 cm\textsuperscript{2} in whom the valve area increased to only 0.7 cm\textsuperscript{2}.

On relatively short follow-up in 62 patients who had had their valvuloplasties 5 months or more before, there was a marked improvement in symptoms with a change from 86% NYHA class III or IV preprocedure to 20% in this severely symptomatic group postprocedure. Angina decreased from 55% preprocedure to 32% postvalvuloplasty. With regard to symptoms, in the 10 patients with postvalvotomy valve areas of less than 0.7 cm\textsuperscript{2}, the valve areas still were increased by 41%, and this resulted in a decrease in symptoms by one or two NYHA classes. In the 62 patients followed a mean of 13 months, late mortality was 39%, which is not different from other studies of patients more than 80 years old who had balloon valvuloplasty.\textsuperscript{14} In Safian and colleagues’ study of 44 patients more than 80 years old, the mortality was 27%.\textsuperscript{8}

It is interesting that no correlation was found between the minimal increase in cardiac output and ejection fraction and the increase in valve area. Other authors have found a slight decrease in cardiac output after the procedure and attributed the drop in gradient to the decrease in output.\textsuperscript{6} This probably indicates that the change in cardiac output may be related to factors other than the change in valve area such as preload, afterload, and contractility changes mediated by blood loss, increased catecholamines, or sympathetic tone.

Another interesting observation is that the predilatation and postdilatation valve areas were similar for those who did well and those who died. Of the 18 who died, 10 still had tight aortic stenoses after valvotomy with valve areas less than 0.7 cm\textsuperscript{2}, even though three had valve areas that had increased by more than 100%. Patients with tight aortic stenoses after valvotomy tended to have a higher death rate with 42% deaths in the 24 patients with valve areas less than 0.7 cm\textsuperscript{2} and 23% deaths in 13 patients with valve areas more than 1 cm\textsuperscript{2}. Because of the small numbers, these death rates were not statistically different, but a trend to better survival with good valve areas after dilatation was present.\textsuperscript{14}

Another problem in relating the late mortality to the success of the valvotomy is that cause of death was frequently not known, and these patients had many conditions unrelated to the valvuloplasty that could have been responsible for a late death. Furthermore, the valve area measurements were made
shortly after the procedure. One of the problems with aortic valvuloplasty, whether operative or nonoperative, is the recurrence rate of severe stenosis. Grollier and colleagues reported 30 patients 75±8.4 years old who had balloon valvuloplasty; 24 also had a hemodynamic study 8 days later. In this study, the peak-to-peak aortic valve gradient dropped from 82±19.9 mm Hg immediately after valvuloplasty; however, at 8 days, the gradient (71±18.8 mm Hg) was almost back to the preprocedure value. The aortic valve area rose from 0.37±0.14 cm² before to 0.60±0.35 cm² after valvotomy and 8 days later had decreased to 0.47±0.10 cm². In this study, cardiac output fell from 3.6±0.9 to 3.3±1.4 L/min after procedure and later went back up to 4.1±1.3 L/min. One possibility is that the drop in the gradient was not associated with the increase in valve area but was related to the decrease in cardiac output; this would not account for the increase in calculated valve area that was observed. It is evident that although there was a 62% increase in valve area, the amount of increase in valve area still left the patient with severe aortic stenosis rapidly decreasing to the original degree of obstruction.

Nishimura and colleagues in an echocardiographic-Doppler assessment of 55 patients who were 80±6 years old also showed a return to prevalvuloplasty valve area and gradient at late follow-up. In this study, the prevalvuloplasty mean aortic gradient was 48±18 mm Hg, which dropped to 33±12 mm Hg after procedure and at follow-up was 46±16 mm Hg. The aortic valve area by continuity equation went from 0.54±0.15 before to 0.85±0.23 cm² after valvotomy and dropped on follow-up to 0.67±0.19 cm². The good results are clearly compromised by a high incidence of early restenosis.

In this group of mainly octogenarian patients who are severely symptomatic with aortic stenosis, the improvement in symptoms after balloon valvuloplasty is really the most important result of this study. This was not a selected group of patients, and patients were not eliminated because of contraindications to balloon valvuloplasty. The surviving patients had a marked improvement of symptoms with only 20% remaining in NYHA class III or IV, whereas 86% had been in this group before valvuloplasty. The inevitability of death as the terminus of life is not changed by the amazing advances in medicine and cardiology that have characterized the past three decades. In this elderly age group with severe aortic stenosis, the quality of the last months of life can be miserable with unremitting congestive heart failure, angina, and syncope and multiple hospitalizations. If balloon valvuloplasty can alter these last years and improve life for these patients, then the procedure, even though its benefits are temporary, should be used in at least this one group of patients as the primary procedure.

References


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