Clinical Investigation

Aortic Stenosis in Elderly Patients Aged 80 or Older
Treatment by Percutaneous Balloon Valvuloplasty
in a Series of 92 Cases

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Very elderly patients with severe aortic stenosis will probably benefit from percutaneous balloon valvuloplasty. Ninety-two patients, aged 80 or older (mean age, 84±3.7 years) and all severely incapacitated (18 with an associated pathologic condition or in critical condition with terminal heart failure), underwent a valvuloplasty procedure. Femoral access was used in all cases except seven (8%), in whom the femoral route had to be abandoned and the brachial approach was used due to severe arterial tortuosity. Peak-to-peak ventriculooaortic gradient decreased from 71±27 to 27±15 mm Hg, and the aortic valve area increased from 0.48±0.16 to 0.91±0.35 cm² (p<0.01). Thirty-two percent had a postprocedure aortic valve area more than or equal to 1 cm². The final valve area was less than or equal to 0.7 cm² in 30% of the patients. There were three deaths (ages, 82, 92, and 98 years) in the procedure room. One stroke occurred 1 day after the procedure. Hematoma or thrombosis at the femoral puncture site was observed in 14 cases (15%), requiring surgical repair in only five cases. Three patients died in the hospital; the total in-hospital mortality was 6.5%. Among the 62 patients about whom information could be obtained at a mean follow-up interval of 13±5 months, there were 18 late deaths (mean age, 85±11 years). The majority of the surviving 44 patients experienced marked symptomatic improvement. The results indicate that balloon valvuloplasty can be offered to very elderly patients with severe aortic stenosis and can produce improvement in hemodynamic and clinical status. (Circulation 1989;80:1514–1520)

In contrast to the remarkable and long-standing results obtained with surgical valve replacement in patients with aortic stenosis (AS), the indications for balloon aortic valvuloplasty as an alternative therapy have yet to be determined. This, in part, is due to the recent introduction of this procedure, which was first performed by our group in September 1985.¹ In some very old patients, however, surgery cannot even be contemplated when there is an absolute contraindication to surgery or when the surgical risk is prohibitive. Although age alone is not an absolute contraindication to surgical valve replacement, there is little doubt that operative and perioperative mortality and morbidity increase with age, with mortality rates as high as 30% in octogenarians.² On the other hand, the disastrous short-term prognosis of severe AS,³,⁴ as well as the distressful condition of most of the patients with this disease, leaves room for an attempt with a nonsurgical procedure to improve the patient. Therefore, it seems to us that elderly patients (80 years old or older) are those most likely to benefit from percutaneous valvuloplasty.

We report a series of 92 patients, aged 80 or older, with severe AS. This group represents one third of our total experience with balloon valvuloplasty at this time.

Patients

Ninety-two patients, all aged 80 years or older, were included in this study. Some of these patients have been previously reported.¹,⁵,⁶ The mean age was 84±3.7 years; the oldest patient was 98 years old. The study group consisted of 33 men and 59 women, representing 31% of the 300 patients who have had valvuloplasty in our department. This was an unselected group because balloon valvuloplasty was performed as the initial therapy in all patients 80 years old or older who presented with symptomatic AS.

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All patients were severely incapacitated. Forty-four were in New York Heart Association (NYHA) functional class III, and 38 were in class IV. Forty-seven (51%) had angina; half of them were in Canadian Heart Association class III or IV. Thirty-one (34%) had previous syncopal attacks. Those who were not in NYHA class III or IV had severe angina, syncope, or both.

Eighteen had an associated pathologic condition (e.g., previous myocardial infarction, respiratory insufficiency, or cancer) or were in very critical condition with terminal heart failure. Because of these additional risks coupled with old age, these patients were not considered to be acceptable candidates for surgical valve replacement.

All patients had marked calcification of the aortic valve; in 30 cases, calcification was massive.

Methods

In most cases (92%) (n=85), the stenotic aortic valve could be crossed by a retrograde approach through the femoral artery with either a 7F Sones catheter or a left Amplatz catheter. The other seven cases were done by the brachial approach with a cutdown to the brachial artery. Difficulties in manipulating the Sones or Amplatz catheters, as well as the balloon catheters, were encountered in about one third of the cases due to severe iliofemoral arterial tortuosity.

Details of the methodology have been published elsewhere.\(^5\),\(^6\) After crossing the aortic valve with a guidewire, a balloon catheter is positioned across the stenosed aortic valve and maximally inflated to exert a strong dilatational force. In approximately the first two thirds of these patients, we used balloon catheters (Mansfield Inc) initially designed for dilatation of the pulmonary valve. These catheters were introduced percutaneously over a guidewire, without the use of a sheath, into the femoral artery or by cutdown to the brachial artery. Progressively larger balloon dilatation catheters were introduced serially using 15-, 18-, and 20-mm sizes, except in the beginning of our experience. In seven cases, we judged the results to be satisfactory after using a 15-mm diameter balloon, and in 21 cases, an 18-mm diameter balloon. In two cases, we used two balloons side by side (10 and 15 mm). For the last 27 patients, the technique was both improved and simplified. Newly designed catheters (Mansfield Inc) with a lower profile and a double-sized balloon (15/20 mm or 18/23 mm) were used. These catheters were introduced through a 14F arterial sheath (Cook Inc). In three of the seven cases using the brachial route, it was impossible to introduce a balloon catheter larger than 18 mm in diameter, which was a limitation to obtaining a satisfactory result.

A supravalvular aortic and a left ventricular angiogram were performed before dilatation in all cases. Cardiac output was measured by the thermodilution technique with a Swan-Ganz catheter. The left ventriculooaortic gradient was measured either through two separate catheters, one in the left ventricle and one in the ascending aorta, or in the most recent patients, through a balloon catheter equipped with two lumens. This newly designed catheter has a distal lumen to measure the left ventricular pressure and the proximal lumen to measure pressure in the ascending aorta. Immediate results of the dilatation were evaluated during the procedure with the simplified Hakki formula,\(^7\) but final results were calculated with the Gorlin formula.\(^8\)

Postdilatation supravalvular angiograms were performed in 56 patients and left ventricular angiograms in 51 patients. Coronary angiograms were obtained in 26 patients who had marked angina.

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**FIGURE 1.** Plots of changes in peak-to-peak gradient and aortic valve area after balloon aortic valvuloplasty (postBAV). Error bars represent SD.

**FIGURE 2.** Pie chart of distribution of aortic valve area obtained after dilatation. Left: Absolute values of aortic valve area are expressed in cm\(^2\). Right: Change in aortic valve area is expressed as percent increase of valve area as compared with initial value. A good result, with an increase greater than or equal to 75% was obtained in 61% of cases.
FIGURE 3. Plot of correlation between initial aortic valve area (AVA base, cm²) and postdilatation valve area (AVA post, cm²). Error bars represent SD.

Statistical calculations were made with the paired Student’s t test and χ² test.

Results

The mean initial peak-to-peak ventriculooaortic gradient and aortic valve area were 71±27 mm Hg and 0.48±0.16 cm², respectively. After dilatation, the transvalvular gradient was reduced to 27±15 mm Hg, and the aortic valve area increased to 0.91±0.35 cm² (p<0.001, for both) (Figure 1). The increase in valve area, however, varied remarkably from patient to patient. The distribution of valve area found after dilatation is shown in Figure 2. Thirty-two percent of the patients had a final aortic valve area more than or equal to 1 cm², and among those, 16% had a final area more than or equal to 1.20 cm². On the other hand, 30% maintained an aortic valve area of 0.7 cm² or less. These results can also be expressed in percent increase over the initial valve area. Some patients have such a tight stenosis that even a 100% increase over baseline can result in a final valve area of 0.7 cm². As shown in Figure 2, 81% of the patients had an increase in valve area of 50% or more, and 43% had an increase of 100% or more. Only 7% had an increase of less than 25%, a result considered clearly insufficient, possibly equivalent to complete failure of the procedure. There was a relatively weak but significant correlation between initial and final areas (Figure 3). The 30 patients with massive valve calcification had a more severe AS than the group with less calcification (0.40±0.13 versus 0.52±0.17 cm², p<0.01). The postdilatation valve area was smaller (0.81±0.24 versus 0.97±0.39 cm², p<0.05), but the percent increase was larger, although not significantly (116±105% versus 92±58%).

Cardiac output and ejection fraction measured immediately after dilatation revealed a slight but significant increase (p<0.05 and p<0.001, respectively) with marked individual variation (Figure 4). There was no correlation between the increase in cardiac output or ejection fraction and the percent increase in valve area. In those 56 patients who underwent a supravalvular aortogram before and after dilatation, aortic regurgitation increased slightly in 14 (25%) and markedly in one (Figure 5).

Complications

There were three deaths in the procedure room within minutes after the dilatation. These patients, who were in a very critical condition, were aged 82, 92, and 98 years. Inflation of the balloon per se had been fairly well tolerated and asystole occurred without clear explanation, especially in one case where a postmortem examination was subsequently obtained.

One patient suffered a transient stroke 1 day after the procedure without CT-scan evidence of calcific embolism. In one case, transient complete atrioventricular block occurred at the time of balloon inflation, requiring placement of a temporary pacemaker. The most frequent complications, hematoma or thrombosis, occurred at the femoral puncture site in 14 cases (15%). Surgical repair was needed in only five cases (6%).

In-Hospital Evolution

The mean hospital stay after valvuloplasty was 7±3 days. After discharge, patients who were not in critical condition before valvuloplasty were able to immediately resume normal activities according to their age. In those patients who were severely incapacitated with symptoms of heart failure, improvement was appreciable within a few days in most cases.

There were three in-hospital deaths. One patient, who was seen in extremis with low cardiac-output symptoms and pulmonary edema, died with recurrent intractable heart failure 6 hours after the dilatation procedure. The valvuloplasty procedure had been very difficult because of severe arterial tortuosity and, in fact, was limited to one inflation with a 15-mm balloon. The aortic valve area was 0.20 cm² initially and had increased to only 0.36 cm². This patient, seen at the beginning of our experience, was the twentieth case in our series. Two patients, aged 84 and 91 years, died of local femoral complications a few days after surgical repair in spite of successful results (final aortic valve areas after

FIGURE 4. Plots of hemodynamic changes after balloon aortic valvuloplasty (postBAV). Cardiac index and ejection fraction increased slightly but significantly.
The total in-hospital mortality rate, including the three procedural deaths, was 6.5%.

Follow-up

To evaluate improvement produced by valvuloplasty, we studied patients in whom the elapsed time between dilatation and inclusion for follow-up was at least 5 months.

We obtained follow-up information on 62 patients at a mean interval of 13±5 months. It is noteworthy that these 62 patients were more severely diseased than the 30 others not included for follow-up because they had their valvuloplasty less than 5 months earlier. Twenty-seven of these 62 patients were in NYHA class IV versus nine among the 30 others. Their initial valve area was 0.46±0.14 versus 0.57±0.20 cm² (p<0.01), and their postdilatation area was 0.85±0.32 versus 1.11±0.32 cm² (p<0.01). There were 18 late deaths (29%); three died within 1 month after the procedure. The mean age for these 18 patients was 85±3 years. It was impossible to accurately determine the cause of death for these 18 patients. Their mean initial and postdilation valve areas were not significantly different from those of the 44 survivors (n=18, 0.42±0.15 cm², initially, and 0.79±0.31 cm², after, versus n=44, 0.47±0.13 cm², initially, and 0.87±0.32 cm², after, p=NS). The procedure was clearly successful in three of these cases, resulting in a final valve area greater than or equal to 1 cm². On the other hand, an inadequate result may have contributed to the death of 10 patients who still had a tight AS after dilatation, with a calculated valve area equal to or less than 0.7 cm², although three of these 10 patients had an increase in valve area of 100% or more. The incidence of postdilatation valve area less than or equal to 0.7 cm² is significantly higher in the deceased group than in the survivors (56% versus 28%, p<0.05). Among the 24 patients who had a postdilatation valve area equal to or less than 0.7 cm², there were 10 deaths (42%). Among the 13 patients who had a postdilatation valve area greater than or equal to 1 cm², there were three deaths (23%). The difference in death rates in these last two subgroups, however, is not significant. Among these 18 patients, seven had angina but only one had a coronary angiogram that showed severe diffuse coronary lesions.

Among the 44 survivors, a marked symptomatic improvement was observed in most of them, as shown in Figure 6. More than two thirds (37 of 44 or 84%) had a clear decrease in dyspnea. Only nine (20%) remained in NYHA functional class III or IV, whereas 38 (86%) were in such classes before dilatation. Although coronary angioplasty was not performed in any case, there was also marked improvement in angina pectoris. Only 14 (32%) had residual angina after valvuloplasty versus 24 (55%) before valvuloplasty. Only four of these patients remained in class III or IV as compared with 12 in these classes before dilatation. Ten patients had a final valve area less than or equal to 0.7 cm², with a 41% increase over initial valve area. They nonetheless experienced a marked clinical improvement with a decrease in dyspnea by one or two NYHA classes. Initial and postdilatation valve areas were not significantly different in the 35 patients with marked improvement in dyspnea and in the nine

**Figure 5.** Changes produced in aortic regurgitation by balloon valvuloplasty. In majority of cases, aortic stenosis was pure and aortic valve remained competent after dilatation.

**Figure 6.** Follow-up in 44 patients. Improvement in dyspnea (left) and angina (right).
patients who remained in NYHA class III or IV \((n=35, 0.48\pm0.13 \text{ cm}^2, \text{ initially, and } 0.88\pm0.31 \text{ cm}^2, \text{ after, versus } n=9, 0.44\pm0.12 \text{ cm}^2, \text{ initially, versus } 0.86\pm0.38 \text{ cm}^2, \text{ after, } p=\text{NS}).

Comments

In elderly patients with AS, balloon valvuloplasty can be performed with relatively low risk and with overall good tolerance of the procedure. For the three patients who died in the procedure room, it is difficult to determine the exact role of the valvuloplasty because death occurred several minutes after the balloon inflations and the patients were critically ill before the procedure. For those three who died in the hospital, death appeared to be related more to poor clinical condition than to the valvuloplasty procedure. The mean age of these six patients was 88±5 years, and all of them were in NYHA class IV. Two had left ventricular ejection fraction below 30%, one necessitating a dobutamine infusion. In one case done early in our experience, only one inflation with a 15-mm balloon could be performed because of severe arterial tortuosity. It did not produce an effective dilatation.

It is also very difficult to draw conclusions regarding the high mortality rate of 29% of the patients during the 13 months of follow-up because the mean age of these 18 patients was 85±11 years, which is clearly above the mean life expectancy of the general population. A similar mortality rate (28%) was observed by Block,\(^9\) but the mean follow-up was 5 months and the mean age was 79 years old. It is likely that the 10 patients whose final valve areas remained at or below 0.7 cm\(^2\) were inadequately dilated. However, death also occurred in three patients in whom the procedure had produced a good result with a valve area greater than or equal to 1 cm\(^2\). Although there was a higher death rate (42%) in patients with a final valve area less than or equal to 0.7 cm\(^2\) than in those (23%) with a final valve area greater than or equal to 1 cm\(^2\), the difference in the two subsets was not significant. Also, because the correlation between the initial and the final valve area is weak although significant (Figure 3), we should not conclude that patients with an extremely tight AS are particularly poor candidates for valvuloplasty. Additionally, it is possible that death could have resulted from restenosis, a phenomenon about which sufficient current information is lacking, particularly in this very elderly patient population, but which seems to be a frequent occurrence after balloon aortic valvuloplasty.\(^9\)

However, such a mortality rate is clearly lower than that for medically treated AS. In two such series of patients\(^3,4\) with a markedly lower mean age (77 and 43 years old) and who were less critically ill, the 1-year death rate was 40–60%.

On the other hand, the functional improvement observed in the majority of the surviving patients is very encouraging. Symptoms of cardiac failure and angina decreased or disappeared in most surviving patients, and syncope did not recur. This clinical improvement confirms the effectiveness of balloon aortic valvuloplasty. Because a valve area less than or equal to 0.7 cm\(^2\) is believed to be a critical stenosis, most of our patients with a mean increase in valve area from 0.48 to 0.91 cm\(^2\) have exchanged an extremely tight stenosis for a clearly milder one. Although a 0.90-cm\(^2\) valve area is clearly a smaller opening than that of a prosthetic valve, such an area is probably sufficient to allow an elderly patient to resume a normal life. Furthermore, we have to consider the individual values of the valve areas obtained. Balloon dilatation produced a good result in 32% of the patients who had a final area more than or equal to 1 cm\(^2\), with a result that can even be said to be excellent in 16% who had an area more than or equal to 1.2 cm\(^2\). On the other hand, the results can be considered poor in 30% of the patients with resulting final valve areas of 0.7 cm\(^2\) or less. It is noteworthy, however, that the benefit produced by the dilatation was not negligible for these patients because eight out of 13 had a 50% or more increase in their aortic valve area. Several of these patients exhibited a marked clinical improvement with only five in dyspnea class III or IV versus 11 before valvuloplasty. Thus, a residual aortic valve area of 0.7 or 0.8 cm\(^2\) is far from ideal, but it may represent a very appreciable clinical improvement if the initial area was 0.3 or 0.4 cm\(^2\). As already suggested by Safian et al,\(^10\) however, we could not find correlation between functional improvement and initial or final valve area.

It is difficult, if not impossible, to compare these results with those of surgical valve replacement, the "gold standard" and, until now, the only effective treatment for AS. The surgical risk in very elderly patients is difficult to evaluate at the present time. A large number of papers on this topic have been published in the last few years, but the upper age limit is usually only 70 years. Even when considering only the series concerning aortic valve replacement performed after 1978–1979 with the use of hypothermic myocardial protection, death rates of approximately 10% are common with this age limit.\(^11–14\) Although there is a current tendency to consider that advanced age alone is not a contraindication to surgical valve replacement, aortic valve replacement studies concerning older patients are scarce. In one series of 100 patients 75 years old or older, the operative death rate was remarkably low at 3%.\(^15\) It must be noted, however, that there were only 19 patients older than 80 years. In a recently published series on open-heart surgery in 100 octogenarians, the death rate at 3 months was 29%.\(^2\) It was similar for the 33 patients who underwent aortic valve replacement only. Furthermore, we emphasize the fact that published operative results are biased because surgeons rightly refuse to operate on patients at high risk. On the contrary, our patients came from an unselected population and were treated with valvuloplasty regardless of the
severity of their medical condition. Moreover, surgery was contraindicated in one fourth of our patients. Although with more recent improvements, the surgical risk is now probably decreased for elderly patients, it is impossible at the present time to compare the results of surgical valve replacement with those of balloon valvuloplasty. Also, one must remember that even if the valvuloplasty results in an inadequate dilatation, the opportunity exists for assessing whether surgical valve replacement should be attempted in those cases in which surgery is not absolutely contraindicated.

If we separate our 92 cases into two groups, the first half corresponding to our initial experience and the second half including the more recent patients, we can see that the results are consistently better in the latter group with a mean final aortic valve area of 1.04 versus 0.80 cm² for the former group. In 50% of the recently treated patients, versus only 14% in the initial group, the aortic valve area was more or equal to 1 cm². Conversely, an area less than 0.7 cm² was calculated in only 11% of the more recent group as compared with 47% in the initial patients (Figure 7). The same improvement in the results is found when the increase in valve area is expressed as a percent increase over the initial area. An increase of less than 25% in the valve area, which can be considered a procedure failure, was not observed in any case among the most recently treated patients, whereas it was seen in 13% of the cases in our initial experience. Therefore, one should expect better clinical results in patients who benefit from the most recent technical improvements.

As stated by Selzer, "the total population with aortic stenosis is probably older (than usually said), considering that many patients with senile aortic stenosis are never referred for presurgical evaluation." The introduction of balloon aortic valvuloplasty and the concomitant development of continuous wave Doppler has broadened the clinical profile of AS in adults with the emergence of diagnostic capabilities and therapeutic considerations for very elderly patients with this disease. Indeed, there is no specific mention of these patients in textbooks or articles on AS, which thereby limits our knowledge of the incidence, clinical aspects, and prognosis of the disease in this subset of patients. For example, in a recent article concerning a series of 253 patients with AS who had coronary angiography during catheterization, the mean age was 63±9 years, with mention of an age limit of 70 years and only 51 patients older than this age. Because very few patients 80 years old or older with AS undergo surgery, we wonder about the outcome of these patients who undoubtedly existed before valvuloplasty was introduced. In our institution, which is the only referral hospital for our region (approximately 1.2 million residents), 104 patients with AS underwent aortic valve replacement during the years 1984–1986. The mean age of these patients was 63±12 years, and only two patients were 80 years old or older (80 and 83 years). The 92 patients aged 80 or older, treated with balloon valvuloplasty and reported here, were studied for two years, from January 1986 to December 1987. Because 47 of them were referrals from outside the region, 45 patients aged 80 years or older came from our area during the 2-year period. It is logical to conclude that before the introduction of valvuloplasty, elderly patients with AS were not effectively treated. This conclusion certainly applies to other institutions because the published surgical series concerning valve replacement only occasionally contains patients this old. It is also likely that, before the current use of continuous wave Doppler, cardiac catheterization was not performed because surgery would not have been considered, and therefore, AS was not diagnosed with certainty in these patients.

AS is a common disease in the elderly, and physicians are frequently faced with a difficult therapeutic challenge. Although surgical valve replacement is the most definitive therapy and can be performed at an acceptable risk in carefully selected elderly patients, the operative risk is often prohibitive and in many such patients surgery cannot be considered. Balloon aortic valvuloplasty can now be offered as a potentially effective treatment that is able to produce an appreciable clinical and hemodynamic improvement in a majority of the patients.

Recently published data suggest a high restenosis rate within a few months, and more data are needed for evaluation of the long-term results of aortic valvuloplasty in elderly patients. In many cases, it may provide, nonetheless, the only reasonable possibility for patient improvement.

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References


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