Doppler Evaluation of Results of Percutaneous Aortic Balloon Valvuloplasty in Calcific Aortic Stenosis

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To evaluate the short-term results of percutaneous aortic balloon valvuloplasty, 55 consecutive elderly patients with symptomatic, severe aortic stenosis who were at high risk for surgical intervention underwent the procedure, with follow-up by clinical evaluation and Doppler echocardiography. Over a mean follow-up of 6.2 months, there were three early deaths (<30 days) and eight late deaths. Nine patients underwent subsequent aortic valve surgery, and four had repeat balloon valvuloplasty. Doppler echocardiography revealed a reduction in aortic valve mean gradient from 48 ± 18 to 33 ± 12 mm Hg after the procedure (p < 0.001) but a return to 46 ± 16 mm Hg at follow-up (p < 0.05). The aortic valve area increased from 0.54 ± 0.15 to 0.85 ± 0.23 cm² after the procedure (p < 0.001), but there was a significant decrease to 0.67 ± 0.19 cm² at follow-up (p < 0.05). Of patients free of aortic valve operation or death after 30 days after the procedure, 76% were severely symptomatic before the procedure as compared with 38% at follow-up. In patients undergoing percutaneous aortic balloon valvuloplasty, there is a continued high short-term mortality and a significant incidence of restenosis over short-term follow-up. Nonetheless, a subset of patients do experience sustained clinical improvement from this procedure. (Circulation 1988;78:791-799)

Percutaneous aortic balloon valvuloplasty is a recently developed technique in which one or more large balloons are inflated across a stenotic aortic valve in an attempt to reduce the severity of stenosis. First described in 1986 by Cribier et al for use in elderly patients with severe, symptomatic calcific aortic stenosis, this technique is now being applied to many such patients. Although initial reports have described a marked improvement in symptomatology in patients undergoing percutaneous aortic balloon valvuloplasty, there have been few studies that have evaluated the outcome of these patients over a follow-up period. The purpose of this prospective study was to determine the results of percutaneous aortic balloon valvuloplasty as assessed by clinical evaluation and Doppler echocardiography.

Patients and Methods

Patient Population

The patient population consisted of the first 55 consecutive patients undergoing percutaneous aortic balloon valvuloplasty at the Mayo Clinic between June 1986 and June 1987 (Table 1). This procedure has been approved by the Institutional Review Board of the Mayo Clinic for patients with symptomatic, severe aortic stenosis who are not surgical candidates because of coexistent medical problems; are at high risk for surgery because of severe left ventricular dysfunction, advanced age, or coexistent medical problems; and refuse surgery. Written, informed consent was obtained from all patients.

The inclusion criteria were strictly maintained. There was no patient undergoing balloon valvuloplasty who was less than 70 years old who was otherwise a good surgical candidate. Of the three patients less than 70, one had a previous mitral valve prosthesis with crippling rheumatoid arthritis and atlanto-occipital instability, one had a previous mitral valve replacement with severe left ventricular dysfunction (ejection fraction, 20%), and the
third had previous coronary artery bypass surgery with patent grafts. There were six patients who underwent balloon valvuloplasty in preparation for noncardiac surgery (three for abdominal surgery, two for orthopedic surgery, and one for a cataract operation). The decision to proceed with balloon valvuloplasty in the remaining 46 patients was based on advanced age, coexistent medical problems, severe left ventricular dysfunction, or a combination of these problems.

The age range was from 64 to 90 years with a mean age of 80 ± 6 years and with a man:woman ratio of 1:2. Thirty-seven patients (68%) were more than 80 years old, and 52 (95%) were more than 70 years old. All patients were symptomatic with 71% having New York Heart Association functional Class III or IV heart failure symptoms and 20% having New York Heart Association functional Class III or IV chest pain. Twenty-two percent of patients had had previous episodes of near-syncope or syncope.

**TABLE 1. Patient Population at Baseline**

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>55</td>
</tr>
<tr>
<td>Age (mean ± SD)</td>
<td>80 ± 6</td>
</tr>
<tr>
<td>Male:female ratio</td>
<td>1:2</td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
</tr>
<tr>
<td>Congestive heart failure, NYHA Class III or IV</td>
<td>71%</td>
</tr>
<tr>
<td>Angina, NYHA Class III or IV</td>
<td>20%</td>
</tr>
<tr>
<td>Syncope</td>
<td>22%</td>
</tr>
<tr>
<td>Hemodynamics</td>
<td></td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>51 ± 17%</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td></td>
</tr>
<tr>
<td>1V</td>
<td>18%</td>
</tr>
<tr>
<td>2V</td>
<td>16%</td>
</tr>
<tr>
<td>3V</td>
<td>5%</td>
</tr>
<tr>
<td>Aortic valve area</td>
<td>0.54 ± 0.15 cm²</td>
</tr>
<tr>
<td>Mean gradient</td>
<td>48 ± 18 mm Hg</td>
</tr>
</tbody>
</table>

mm (two patients), 20 mm (four patients), and 23 mm (two patients) and two balloons of 15 and 12 mm (eight patients), 15 and 15 mm (25 patients), 15 and 18 mm (nine patients), and 12 and 20 mm (two patients). The lengths of the 15-, 18-, and 20-mm balloons were 3.0 or 5.5 cm, and the length of the 23-mm balloon was 3.0 cm.

For each patient, three initial inflations were performed with a 15-mm balloon. If the catheter-derived peak-to-peak gradient had not decreased by 50% or was more than 40 mm Hg, then additional inflations were performed with either a larger single balloon or dual balloons. The duration of each inflation was 1 minute unless there was hemodynamic compromise during the inflation, necessitating a shorter inflation duration. The inflations had to be terminated early in 30% of inflations with the larger single balloons (20 and 23 mm) or the dual balloons.

At the end of the procedure, repeat aortic valve areas were calculated. An aortic root angiogram was performed unless there was severe hemodynamic compromise or chronic renal failure present (52 patients). All patients were sent to the intensive care unit for 24-hour monitoring and then dismissed to a regular hospital floor bed.

**Doppler Echocardiography**

Cardiac catheterization has been the procedure of choice in the past for determination of aortic valve hemodynamics. However, the accuracy of Doppler echocardiography in assessment of aortic valve gradients and aortic valve area has recently been validated.8–13 Because Doppler echocardiography allows serial noninvasive measurements in this critically ill, elderly population, two-dimensional and Doppler echocardiograms were performed during three time periods: within 24 hours before the procedure, 24–48 hours after the procedure, and at later follow-up. From a two-dimensionally directed M-mode at midcavity level, an ejection fraction was calculated with a modification of the method described by Quinones et al.14 A measurement of the left ventricular outflow tract diameter was obtained from a systolic two-dimensional freeze-frame in the parasternal long-axis view with the on-line measurement software package. The diameter was taken from the point of insertion of the aortic valve cusps into the aortic anulus. A left ventricular outflow tract velocity was measured by pulsed-wave Doppler echocardiography from the apical position, placing the sample volume in the left ventricular outflow tract just proximal to the region of high-velocity turbulence through the aortic valve. A nonimaging, continuous-wave probe was used to measure the velocity across the aortic valve. Multiple transducer positions were used to find the highest velocity jet, as described previously.13,15

For each time period, the signals with the highest velocity and well-defined spectral envelope were taken. The studies in which the spectral envelope was not well defined were excluded from analysis.
In patients with atrial fibrillation (10 patients), an average of 10 beats was used. The aortic valve velocity curve was digitized onto an off-line computer system for calculation of the mean aortic valve gradient, as previously described. An aortic valve area was calculated from the continuity equation, as shown:

\[
AVA = \frac{\text{peak vel LVO} \times (LVO \text{ diam}/2)^2 \times \Pi}{\text{peak vel AV}}
\]

where \(AVA\) is aortic valve area, peak \(LVO\) is peak left ventricular outflow velocity, LVO diam is diameter of the left ventricular outflow tract, and peak \(AV\) is peak aortic valve velocity. Complete Doppler information was available in 51 (91%) of 55 patients before the procedure, 46 (85%) of 54 patients after the procedure, and 33 (94%) of 35 patients at follow-up. Thirty patients had complete Doppler hemodynamics at all three time periods.

Restenosis of the aortic valve was defined as follows. The difference between the aortic valve area measured before and 24–48 hours after the procedure was taken as the absolute initial improvement in valve area. If the final aortic valve area was less than the sum of the preprocedure valve area plus 50% of the initial improvement, then restenosis was said to be present. For example, if the initial aortic valve area was 0.50 cm² with an increase in valve area to 0.80 cm² at 24–48 hours after valvuloplasty, restenosis was present if the valve area at follow-up was less than 0.65 cm².

Follow-up

Follow-up was obtained in the following manner. Telephone calls were made to the patient at 1- and 3-month intervals after the procedure. If there were symptoms of increasing heart failure or angina, the patient returned for a follow-up examination. If the patient remained stable, he or she was asked to return at 4–6 months after the procedure when a complete cardiovascular examination was performed. At each visit, a repeat two-dimensional and Doppler echocardiogram was performed by one of the investigators. Two patients underwent cardiac catheterization for evaluation of hemodynamics instead of Doppler echocardiography.

Endpoints included death, aortic valve operation, repeat percutaneous aortic balloon valvuloplasty, and clinical status at 4–6-month follow-up. There were six patients who could not return for a complete hemodynamic evaluation but had evaluation of their clinical status by telephone interview by one of the investigators. There were seven patients who died and two who underwent aortic valve operation whose clinical status was available before the event but in whom a complete follow-up Doppler echocardiographic evaluation was not obtained.

Statistics

Changes in hemodynamic variables were tested on a “per comparison” basis with paired \(t\) tests for comparisons deemed a priori to be of interest. In the subset of patients with values of the hemodynamic variables recorded on all three time periods (before, after, and follow-up), changes in time were tested on a “per experiment” basis with repeated measures of analysis of variance, with the Student-Newman-Keuls procedure as a multiple comparison test. Comparison of aortic valve area calculated by catheterization versus that obtained by Doppler echocardiography was made with linear regression. Significance was set at the \(p<0.05\) level.

**Results**

**Baseline Hemodynamic Characteristics**

The baseline hemodynamic profile of the patient population is shown in Table 1. The mean ejection fraction was 51%. However, 16 patients (29%) had an ejection fraction of less than 40%, and nine patients (16%) had an ejection fraction of less than 30%. Coronary artery disease, defined as equal to or more than 70% luminal diameter narrowing, was present in 40% of patients (one-vessel, 10 patients; two-vessel, nine patients; three-vessel, three patients). The mean aortic valve gradient measured by Doppler echocardiography ranged from 20 to 105 mm Hg, with an average of 48 ± 18 mm Hg. The peak left ventricular outflow velocity, which reflects stroke volume through the aortic valve, averaged 0.74 ± 0.21 m/sec. Twenty-five patients (45%) had a peak left ventricular outflow velocity of equal to or less than 0.7 M/sec, indicating a low output state. The Doppler-derived aortic valve area averaged 0.54 ± 0.15 cm².

**Procedural Complications**

There was one death directly related to the procedure as a result of perforation of the left ventricle resulting in acute cardiac tamponade followed by electrical-mechanical dissociation (Table 2). There was one episode of hemodynamic compromise occurring 1 day after the procedure because of a new pericardial effusion that required pericardiocentesis. An emergency percutaneous transluminal coronary angioplasty was performed in one patient after completion of balloon valvuloplasty because of significant chest pain and electrocardiographic

**Table 2. Procedural Complications of Percutaneous Aortic Balloon Valvuloplasty**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Patients (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular complications—no surgery required</td>
<td>9</td>
</tr>
<tr>
<td>Vascular complications—surgery required</td>
<td>6*</td>
</tr>
<tr>
<td>Visual defects</td>
<td>3</td>
</tr>
<tr>
<td>Tamponade</td>
<td>2</td>
</tr>
<tr>
<td>Loss of consciousness</td>
<td>2</td>
</tr>
<tr>
<td>Emergency PTCA</td>
<td>1</td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td>1</td>
</tr>
<tr>
<td>Sepsis</td>
<td>1</td>
</tr>
</tbody>
</table>

*One death; †one late onset.
changes during and after balloon inflation. A successful dilatation of a 90% left anterior descending coronary artery lesion was performed without sequelae. One episode of pulmonary edema occurred during balloon valvuloplasty in a patient with an ejection fraction of 15%, which responded to diuresis. There were three patients who developed transient visual field defects during the procedure. In two of the three patients, these resolved completely. The third patient developed a permanent homonymous hemianopsia. Two patients experienced transient loss of consciousness during balloon inflation, but no residual effects were noted.

There was one patient who had moderately severe aortic regurgitation after the procedure. The remaining patients had a trivial-to-mild degree of aortic regurgitation after balloon valvuloplasty as assessed by aortic root angiography.

Immediate Hemodynamic Results

Doppler echocardiographic studies done at 24–48 hours after the procedure revealed a decrease in the mean gradient from 48 ± 18 to 33 ± 12 mm Hg (p < 0.0001) (Figure 1). The left ventricular outflow velocity increased from 0.74 ± 0.21 to 0.92 ± 0.21 m/sec (p < 0.0001). This resulted in an improvement in the calculated aortic valve area from 0.54 ± 0.15 to 0.85 ± 0.23 cm² (p < 0.0001) (Figure 2).

Comparison of Aortic Valve Area Derived by Catheterization Versus Doppler Echocardiography

Figure 3 (left) illustrates the aortic valve area derived by catheterization versus that derived by Doppler echocardiography before the valvuloplasty procedure. Twenty-five Doppler echocardiographic studies were performed at the time of cardiac catheterization. The remaining 25 Doppler echocardiographic studies were done within 24 hours before the procedure. Figure 3 (right) demonstrates the aortic valve area by catheterization versus Doppler echocardiography after the procedure. The catheterization data were obtained immediately after the procedure, and the Doppler echocardiographic studies were performed 24–48 hours after the procedure.

In-Hospital Course

There were five patients who required vascular surgery during the hospital stay for the development of a hematoma or pseudoaneurysm. Another nine patients developed large hematomas but did not require surgery. One patient developed a low-grade fever and had a Gram-negative bacillus cultured from his blood. After treatment with intravenous antibiotics, there was no further evidence of infection. There were two patients who underwent aortic valve operation during the hospitalization, one because of inadequate hemodynamic results and the other because of continued symptoms of heart failure. One of these patients died after surgery because of cerebral anoxia from the operation.

There were two more deaths during the first 30 days after the procedure. One 77-year-old woman fell 1 week after the procedure and became bedridden because of a hip fracture. She subsequently developed a large cerebrovascular accident and died several days later. A second patient died suddenly while undergoing a bowel preparation for an abdominal operation several weeks later.

All five patients who survived to undergo noncardiac surgery did well during their respective opera-
tions. There were no episodes of hemodynamic compromise or pulmonary edema during or after surgery.

Follow-up

Follow-up was obtained on all 50 remaining patients (100%). There were eight deaths in the follow-up period (Table 3). Five deaths were because of progressive congestive heart failure at 2 (three patients), 4, and 5 months. One death was believed to be of a noncardiac etiology. This was in an 89-year-old man who developed severe depression and progressive lethargy without evidence of cardiac decompensation. There were two patients who had a change in mental status after the procedure. One of the patients had a new homonymous hemianopsia, but there were no other focal deficits. The other patient was found to have no focal neurological deficits. However, each patient experienced a progressive downhill course with mental deterioration and return of heart failure, eventually dying at 1 and 5 months, respectively, after the procedure. Of the seven patients who died with congestive heart failure, all were in New York Heart Association functional Class III or IV before the procedure, and five of seven had an ejection fraction equal to or less than 35%. All seven patients died before a repeat Doppler echocardiographic examination could be performed. The mean follow-up period of the surviving 42 patients was 6.2 months.

Initial subjective clinical improvement was noted by all patients. However, symptoms were noted to return in many patients by the time of follow-up. Figure 4 demonstrates the symptomatic status of the 50 patients at the time of follow-up or immediately before death. Of 38 patients (76%) who initially were severely symptomatic with heart failure symptoms or angina (New York Heart Association functional Class III or IV), 20 patients had sustained, significant relief of symptoms. However, 18 patients with transient improvement returned to their previous functional class, and one patient who was mildly symptomatic before the procedure was severely symptomatic at follow-up. Therefore, a total of 19 patients (38%) had New York Heart Association functional Class III or IV symptoms at follow-up. There were 11 patients who had experienced near-syncope or syncope before the procedure, and one patient with near-syncope during the follow-up period.

Seven patients underwent subsequent aortic valve replacement. Four were because of stenosis and recurrence of symptoms. Three patients underwent aortic valve replacement because of inadequate hemodynamic results, although they had remained free of significant symptoms by the time of operation. One of these three patients required concurrent vascular operation for the late occurrence of bilateral hematomas. There were no deaths during surgery.

A repeat balloon valvuloplasty was performed in four patients at 5.0, 6.5, 7.0, and 10.5 months, respectively, because of severe, recurrent heart failure. All four patients had experienced initial relief of symptoms. One patient died suddenly 4 days after the second valvuloplasty from hyperka-

![Figure 3. Plots of comparison of the aortic valve area derived by catheterization versus that derived by Doppler echocardiography obtained before the valvuloplasty procedure (left) and after the valvuloplasty procedure (right). The line of identity (y = x) and the regression lines are shown. AVA, aortic valve area; cath, catheterization-derived values.](http://circ.ahajournals.org/figure/3/)

![Figure 4.](http://circ.ahajournals.org/figure/4/)

**TABLE 3.** Late Mortality

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Sex</th>
<th>NYHA Class</th>
<th>EF (%)</th>
<th>Gradient (mm Hg) Before</th>
<th>After</th>
<th>AVA (cm²) Before</th>
<th>After</th>
<th>Cause of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>82</td>
<td>M</td>
<td>2</td>
<td>49</td>
<td>56</td>
<td>36</td>
<td>0.48</td>
<td>0.94</td>
<td>Noncardiac</td>
</tr>
<tr>
<td>2</td>
<td>82</td>
<td>M</td>
<td>4</td>
<td>60</td>
<td>80</td>
<td>50</td>
<td>0.65</td>
<td>1.0</td>
<td>CHF</td>
</tr>
<tr>
<td>3</td>
<td>83</td>
<td>M</td>
<td>4</td>
<td>25</td>
<td>22</td>
<td>13</td>
<td>0.43</td>
<td>0.70</td>
<td>CHF</td>
</tr>
<tr>
<td>4</td>
<td>84</td>
<td>M</td>
<td>4</td>
<td>30</td>
<td>36</td>
<td>27</td>
<td>0.33</td>
<td>0.68</td>
<td>CHF</td>
</tr>
<tr>
<td>5</td>
<td>62</td>
<td>F</td>
<td>4</td>
<td>21</td>
<td>34</td>
<td>22</td>
<td>0.44</td>
<td>0.67</td>
<td>CHF</td>
</tr>
<tr>
<td>6</td>
<td>71</td>
<td>M</td>
<td>3</td>
<td>15</td>
<td>33</td>
<td>20</td>
<td>0.65</td>
<td>1.15</td>
<td>Mental change, CHF</td>
</tr>
<tr>
<td>7</td>
<td>84</td>
<td>F</td>
<td>3</td>
<td>64</td>
<td>28</td>
<td>24</td>
<td>0.60</td>
<td>0.68</td>
<td>Mental change, CHF</td>
</tr>
<tr>
<td>8</td>
<td>86</td>
<td>M</td>
<td>4</td>
<td>35</td>
<td>42</td>
<td>31</td>
<td>0.60</td>
<td>0.86</td>
<td>CHF</td>
</tr>
</tbody>
</table>

NYHA, New York Heart Association Class heart failure and/or angina before the procedure; EF, ejection fraction; gradient, aortic valve mean gradient before and 24–48 hours after procedure; AVA, aortic valve area; CHF, heart failure.
Two patients have had sustained improvement of symptoms 1 and 2 months, respectively, later, but the third patient has developed severe heart failure 4 months after the procedure.

Doppler echocardiographic data at follow-up was available in 35 patients. The aortic valve mean gradient was $46 \pm 16$ mm Hg, the peak left ventricular outflow velocity was $0.89 \pm 0.21$ m/sec, and the aortic valve area was $0.67 \pm 0.19$ cm$^2$. In the 30 patients who had complete hemodynamic data before valvuloplasty, 24–48 hours after the procedure, and at follow-up, there was a significant difference in the mean aortic valve gradients and aortic valve areas over these three time periods. All three time periods were significantly different for these two variables ($p<0.05$, Student-Newman-Keuls test). The aortic valve mean gradient at follow-up was significantly higher than 24–48 hours after the procedure but lower than before the procedure (Figure 1). The aortic valve area at follow-up was significantly lower than 24–48 hours after the procedure but higher than before the procedure (Figure 2). The peak left ventricular outflow velocity at follow-up was not significantly different than either before the procedure or 24–48 hours after the procedure.

Restenosis was diagnosed in 19 patients (63% of those who had complete hemodynamic information at all three time periods). In evaluating the subgroup of patients with mild or no symptoms of angina or heart failure at follow-up (New York Heart Association functional Class I or II), there were nine patients (47%) who met the criteria for restenosis.

The overall results of the outcome of patients with percutaneous aortic balloon valvuloplasty are shown in Figure 5. Of the initial 55 patients, there were a total of 11 deaths (20% mortality). Nine patients underwent subsequent aortic valve replacement, and four had repeat valvuloplasty. In the remaining 31 patients, there are 27 patients who have remained relatively free of symptoms. Therefore, of the initial 55 patients who underwent aortic balloon valvuloplasty, 49% have experienced improvement in symptomatology at the time of last follow-up.

**Discussion**

Percutaneous aortic balloon valvuloplasty of severely calcific aortic valves in the elderly population was met with a high degree of initial enthusiasm when it was shown that dramatic improvement in symptomatology could be achieved in the severely symptomatic patient.1–4 Within the last decade, there have been a growing number of elderly patients who present with severe, symptomatic aortic stenosis.18 Because these elderly patients with multiple medical problems are believed to be at a higher risk for surgical intervention, there was a high expectation for percutaneous aortic balloon valvuloplasty. However, as with any new interventional technique, a critical analysis of the short- and long-term results are needed before a procedure can be confidently applied to a group of patients to achieve a beneficial effect.5,7 The results of this study suggest that this technique may not be as beneficial as previously expected. The high continued mortality rate seen in this study has been documented by others,19–22 especially in patients with left ventricular dysfunction.23,24 There have also been recent reports confirming the presence of a high restenosis rate after aortic balloon valvuloplasty.19–21,25–27

The mortality and morbidity in this group of patients, however, should not be compared with previous surgical literature. Because of the highly selective inclusion criteria in this study, the majority of patients were more critically ill at presentation than in any comparable surgical series. Many patients had end-stage aortic valve disease when the ventricle was already failing, as evidenced by the percentage of patients with low ejection fractions and severe heart failure. In addition, many
patients were elderly and had coexistent medical problems that makes them at higher risk for the surgery.\textsuperscript{28,29} Without any intervention, a comparable subgroup of patients has been demonstrated to have a dismal outlook, with a 37\% 2-year mortality.\textsuperscript{30}

Because of the long-standing underlying disease processes and high restenosis rate in this group, balloon valvuloplasty may not be able to improve mortality, as evidenced by the high mortality rate in this series. However, subjective functional improvement can occur for a period of time. Many patients with only a modest improvement in valve area can achieve dramatic symptomatic improvement. Rahimtoola\textsuperscript{6} has speculated that there is a "critical" level of stenosis that causes rapid deterioration. If a small increase in valve area from percutaneous aortic balloon valvuloplasty alters the loading condition of the ventricle, it may be sufficient to improve hemodynamics and symptoms in certain subsets of patients.\textsuperscript{6}

It is important to distinguish between "restenosis," as assessed by hemodynamic data, and "clinical restenosis," which considers the symptomatic response to this procedure. There were many patients in this study who continued to experience symptomatic improvement despite restenosis of the valve area during follow-up. In this elderly, high-risk population, such palliation of symptoms may be an acceptable goal of this therapeutic endeavor.

The population of elderly patients with severe aortic stenosis requiring treatment before noncardiac surgery may represent a new indication for balloon valvuloplasty. Goldman et al\textsuperscript{31} have shown that patients with severe valvular aortic stenosis are at high risk during noncardiac surgery. Although the number of patients is small, all of the patients who underwent noncardiac surgery after balloon valvuloplasty survived without complications.

There were complications of percutaneous aortic balloon valvuloplasty noted in this study. A relatively high incidence of peripheral vascular complications requiring vascular surgery was present because of the large size of the balloons required for this procedure, which has been experienced by others.\textsuperscript{19} It is hoped that with newer technology, one will be able to use larger balloons that can fit through smaller sheaths. Perforation of the left ventricle during the procedure, although infrequent, can occur, resulting in cardiac tamponade. There were two patients who had a permanent change in mental status after the procedure, which could have been the result of multiple small calcific cerebral emboli.

There are potential problems when using Doppler echocardiography for assessment of aortic valve hemodynamics. This is particularly true for evaluating the results of a procedure such as percutaneous aortic balloon valvuloplasty, in which the changes in aortic valve area are relatively small. When applying the simplified Bernoulli equation to estimate the pressure drop across a stenotic aortic valve, there are many assumptions that are made.\textsuperscript{32} Energy loss across the stenosis, pressure recovery distal to the stenosis, acceleration of blood flow, and the velocity of blood proximal to the stenosis are all factors that are neglected when using the simplified Bernoulli equation. This may result in an overestimation of the aortic valve gradient in mild degrees of stenosis, as well as an underestimation of the gradient in severe stenosis.\textsuperscript{32} The measurement of aortic valve gradient depends on the Doppler beam being directed as parallel as possible to the blood flow jet across the aortic valve.\textsuperscript{13,15} This requires the use of a small, nonimaging transducer with multiple angulations from various positions to obtain the highest velocity of blood flow. Small errors in measurement of left ventricular outflow tract diameter may cause larger errors in calculation of aortic valve area because it is the square of the diameter that is used in the continuity equation. Nonetheless, if the Doppler examination is performed by well-trained, experienced echocardiographers, it is believed that accurate assessment of mean aortic valve gradient\textsuperscript{13} and aortic valve area\textsuperscript{8–12,33} can be achieved. The strengths of the continuity equation may be particularly important in the presence of coexistent aortic regurgitation, as well as in the large subgroup of patients with low output states.\textsuperscript{34}

There was a poorer correlation between the catheter-derived and Doppler-derived aortic valve areas in this study when taken after the valvuloplasty procedure. We\textsuperscript{35} and others\textsuperscript{36,37} have previously shown that there is a changing hemodynamic milieu in the first few hours immediately after the procedure, which may be related to transient left ventricular dysfunction. This results in significant changes in cardiac output, mean aortic valve gradient, and aortic valve area over a 24-hour period after the procedure. Therefore, it was believed that a Doppler-derived aortic valve area and mean aortic valve gradient performed at 24–48 hours after the procedure would provide a better representation of the immediate results of aortic valvuloplasty.

Percutaneous aortic balloon valvuloplasty is a new technique whose ultimate clinical role is not fully defined. Symptomatic improvement with modest hemodynamic change has been observed; it may be temporary. Acute complications, although not negligible, are probably less than those for aortic valve surgery in elderly, critically ill patients. Limiting balloon valvuloplasty to elderly, high-risk patients with advanced disease may, by virtue of selection, unfairly bias results against the technique. On the other hand, it is difficult to support the procedure in younger, healthier patients (in whom valvuloplasty might produce better results) because surgical intervention in these patients can be accomplished with low risk and excellent long-term results. Continuing critical evaluation, both symptomatic and hemodynamic, will be crucial in better defining the outcome of and indications for percutaneous aortic balloon valvuloplasty. In addi-
tion, further improvements in technology, as well as advances along the "learning curve" of this technique, may improve results in the future. Until then, we believe that balloon valvuloplasty should be limited to the severely symptomatic, elderly patient who is a high-risk candidate for aortic valve surgery, the severely symptomatic patient who has a limited lifespan because of other medical problems, and the elderly patient who requires palliation of aortic stenosis before noncardiac surgery.

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We acknowledge Dr. Roy S. Small and Dr. Craig Taylor for their professional assistance, Ms. Patricia J. Wagner and Ms. Susan M. Brevig for their assistance in data gathering, and Ms. Denise A. Skoda for her secretarial preparation of this manuscript.

Appendix 1
This table indicates the sizes of balloons used with the dual-balloon technique and the resultant effective diameter that would be obtained using the equations suggested by Yeager et al.38,39

<table>
<thead>
<tr>
<th>Balloon 1 diameter (mm)</th>
<th>Balloon 2 diameter (mm)</th>
<th>Effective diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>15</td>
<td>22.1</td>
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