Combined percutaneous aortic valvuloplasty and transluminal coronary angioplasty in adult patients with calcific aortic stenosis and coronary artery disease

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ABSTRACT Of 120 consecutive balloon aortic valvuloplasty procedures for critical aortic stenosis, valvuloplasty was performed in combination with coronary angioplasty in nine patients (average age 76 years). All nine patients were symptomatic with angina and congestive heart failure before combined procedures. Aortic valvuloplasty was performed with 20 to 23 mm balloon catheters advanced retrogradely from the femoral artery and resulted in an improvement in peak aortic valve gradient (60 ± 19 to 33 ± 13 mm Hg; p ≤ .01) and calculated aortic valve area (0.7 ± 0.1 to 1.1 ± 0.3 cm²; p ≤ .01). Single-vessel coronary angioplasty was performed via the femoral approach, with 2.0 to 3.5 mm balloon catheters, and resulted in a mean reduction of a critical coronary stenosis in each patient from 91 ± 4% to 29 ± 8%. The site of coronary angioplasty was the left anterior descending artery in three patients, the circumflex artery in three patients, the right coronary artery in two patients, and a bypass graft to the right coronary artery in one patient. Combined procedures were performed with a mean arterial time of 108 min. Complications included groin hematomas (n = 2), transient left bundle branch block (n = 1), and transient atrial fibrillation (n = 1). No patient experienced prolonged chest pain, myocardial infarction, major increase in aortic insufficiency, or embolic phenomena. Eight of the nine patients treated with combined procedures noted significant improvement in symptoms of angina and congestive heart failure and were discharged. The ninth patient experienced persistent angina and was treated successfully with aortic valve replacement and coronary artery bypass grafting. Clinical follow-up at a mean of 6 months after procedure has revealed persistent clinical improvement in seven patients, with both valvular and coronary restenosis occurring in one patient. We conclude that combined percutaneous aortic valvuloplasty and coronary angioplasty may be performed safely in adult patients with calcific aortic stenosis and anatomically suitable, single-vessel coronary artery disease. This procedure may be useful in the treatment of selected patients who refuse or who are deferred from surgical intervention because of high operative risk. Circulation 76, No. 6, 1298-1306, 1987.

SURGICAL MORTALITY for aortic valve replacement in patients with isolated aortic stenosis is in general quite low, ranging from 1% to 5%.

The presence of coexisting coronary artery disease and the subsequent need for additional coronary artery bypass grafting, however, may significantly raise the surgical risk, particularly in elderly patients. In a recent report on 259 consecutive patients undergoing aortic valve replacement, overall operative mortality was 6.9%, compared with 13.5% in patients undergoing aortic valve replacement combined with coronary artery bypass. Also of interest was the substantial increase in surgical risk for patients over 70 years of age, who had an operative mortality of 16.9%. Additional medical conditions such as congestive heart failure, pulmonary disease, and renal insufficiency may further raise the risk of surgical intervention.

Previous reports by our laboratory and others.
have recently documented the utility of balloon aortic valvuloplasty as a palliative treatment for elderly patients with calcific aortic stenosis who refuse or who are deferred from aortic valve replacement. The efficacy of transluminal coronary angioplasty has likewise been documented in the elderly population.\textsuperscript{12, 13} The purpose of this study was to assess the potential utility of using both of these procedures in treating adult patients with combined valvular and coronary artery disease.

Methods

**Study group.** Combined aortic valvuloplasty and coronary angioplasty were performed in nine patients with critical, calcific aortic stenosis and coronary artery disease. The study group consisted of six women and three men with a mean age of 76 years (range 53 to 90). All patients were symptomatic with angina, dyspnea on exertion, and weakness. Angina was associated in all patients with transient electrocardiographic changes. Seven patients had a prior history of pulmonary edema; in each case, pulmonary edema occurred after prolonged anigeral episodes. Four patients had a prior history of a subendocardial myocardial infarction and continued to experience postinfarction angina with transient electrocardiographic changes in the area of their previous infarction. Two patients had previously undergone coronary artery bypass grafting. One patient was in atrial fibrillation, and the remainder were in normal sinus rhythm.

All patients were offered surgical intervention with an estimation of their operative risk, but refused surgery. Major reasons for deferring surgery included age greater than 80 years (n = 4), prior coronary artery bypass grafting (n = 2), and weakened and debilitated condition (n = 3).

Each patient subsequently elected to undergo combined balloon aortic valvuloplasty/coronary angioplasty after being informed of the potential risks and complications according to a protocol approved by the Human Studies Committee of the Beth Israel Hospital.

Clinical characteristics of the study group are summarized in table 1.

**Percutaneous angioplasty/valvuloplasty protocol.** Eight of the nine patients underwent combined angioplasty/valvuloplasty as a single procedure, as described below. One patient (No. 4, tables 1 to 3) underwent two procedures, involving initial aortic valvuloplasty followed by coronary angioplasty 10 days later. In this patient, recurrent episodic weakness persisted after aortic valvuloplasty and subsequently improved after coronary angioplasty.

Each patient was brought to the cardiac catheterization laboratory where, after the administration of a local anesthetic, a left radial cannula was placed, the left femoral vein was instrumented with a No. 8F Hemaquét sheath (USCI), and the right femoral artery was instrumented with a No. 9F Hemaquét sheath. Right heart catheterization was performed from the left groin with a No. 7F flow-directed Pace wedge balloon-tipped catheter (Elecath). Continuous pulmonary artery and systemic arterial pressures were monitored throughout the course of the protocol. All patients were anticoagulated with 10,000 to 15,000 U of heparin intravenously, depending on the length of the procedure.

After placement of the right heart catheter, a No. 9F angioplasty guiding catheter (ACS) was passed from the right groin and used to engage the coronary or graft ostia; a No. 9F JR4 was used in the patients with a right coronary artery lesion and in the patient with a graft stenosis, and a No. 9F JL4 was used in the patients with either left anterior descending or circumflex lesions. In each patient, a 0.018 inch high-torque floppy guide wire (ACS) was advanced into the coronary artery past the coronary stenosis, followed by placement of a 2.0 to 3.0 mm Simpson-Robert angioplasty catheter (ACS) at the site of the coronary stenosis. After initial dilatation of the coronary stenosis, a 0.018 inch exchange wire was used to replace the high-torque floppy guide wire, the angioplasty catheter was withdrawn, and repeat coronary angiography was performed. Additional dilations with larger balloon sizes were performed if necessary until the coronary stenosis had been dilated to less than a 50% residual. The angioplasty catheters and guidewires were then withdrawn and repeat coronary injections were made over a period of 15 to 30 min to ensure continued patency of the dilated segment. At the end of the procedure, coronary stenoses were graded visually by two separate observers and were measured as percent narrowing of the luminal diameter.

After coronary angioplasty, the No. 9F guiding catheter was removed, the No. 9F arterial sheath was replaced with a No. 12F sheath (UMI), and a No. 7F pigtail catheter (USCI) was placed in the ascending aorta. The aortic valve was subsequently crossed in each patient with a 0.038 inch straight guidewire to place the pigtail catheter into the left ventricle. Baseline recordings were made of left ventricular and aortic pressure, and cardiac output was measured by the Fick method to allow calculation of the prevalvuloplasty aortic valve area. After baseline measurements, a 0.038 inch exchange wire was placed in the left ventricle. The pigtail catheter and No. 12F sheath were removed, and a 20 mm valvuloplasty catheter (Meditech) was inserted percutaneously into the femoral artery and advanced over the guidewire until centered within the aortic valve. A series of three balloon dilatations were then performed by hand injection of a saline/contrast mixture. The duration of each balloon inflation ranged from 15 to 60 sec, depending on the patient's arterial blood pressure response. After dilatation with the 20 mm balloon, the valvuloplasty catheter was exchanged for the 0.038 inch guidewire, the No. 12F sheath and pigtail catheter were reinserted, and repeat measurements of the aortic gradient were made. If a residual gradient of greater than 50 mm Hg remained and if inflations with the 20 mm balloon were well tolerated with minimal decrease in arterial blood pressure, the valvuloplasty procedure was repeated with a 23 mm balloon. In patients in whom there was a gradient greater than 50 mm Hg after dilatation with the 20 mm balloon and in whom inflation of 20 mm balloon resulted in significant hypotension, the 23 mm

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**TABLE 1**

Clinical characteristics of patients undergoing combined valvuloplasty/angioplasty

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yr)</th>
<th>Sex</th>
<th>Symptoms</th>
<th>Associated disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>81</td>
<td>F</td>
<td>a,c</td>
<td>Prior MI</td>
</tr>
<tr>
<td>2</td>
<td>81</td>
<td>M</td>
<td>a,c</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>77</td>
<td>F</td>
<td>a,c,s</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>71</td>
<td>F</td>
<td>a,c</td>
<td>s/p CABG</td>
</tr>
<tr>
<td>5</td>
<td>90</td>
<td>F</td>
<td>a,c</td>
<td>Prior MI</td>
</tr>
<tr>
<td>6</td>
<td>53</td>
<td>M</td>
<td>a,c</td>
<td>Prior MI, s/p CABG, aifb</td>
</tr>
<tr>
<td>7</td>
<td>79</td>
<td>F</td>
<td>a,c</td>
<td>Prior MI</td>
</tr>
<tr>
<td>8</td>
<td>78</td>
<td>M</td>
<td>a,c</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>71</td>
<td>F</td>
<td>a,c</td>
<td></td>
</tr>
</tbody>
</table>

a = angina; aifb = atrial fibrillation; c = congestive heart failure; CABG = coronary artery bypass grafting; MI = myocardial infarction; s = syncope; s/p = status post.
balloon was not used in order to prevent "over distension" of the aortic anulus. After valve dilatation, repeat measurements were made of pressures and cardiac output to determine a postvalvuloplasty aortic valve area. Each patient was subsequently transferred to the coronary care unit and infusion of heparin was continued until the following morning, when arterial and venous sheaths were removed.

Of note, neither left ventriculography nor supravalvular aortography was performed in any patient; the rationale for not performing these procedures was to eliminate excess contrast load and to minimize the arterial time of the combined angioplasty/valvuloplasty procedure. As an alternative, serial changes in left ventricular ejection fraction, mitral regurgitation, and aortic insufficiency were assessed by serial radionuclide ventriculography and echocardiographic/Doppler studies (see below).

**Serial radionuclide ventriculography.** All patients underwent serial radionuclide ventriculography 24 hr before and 48 hr after combined valvuloplasty/angioplasty procedures. Each patient was injected with 0.75 GBq (20 mCi) of technetium-99m-labeled autologous red blood cells, with technique used for labeling in vitro. Radionuclide ventriculograms were obtained with the patient in a supine position in the anterior, left posterior oblique, and modified left anterior oblique views with a mobile Anger camera computer system (Technicare 410) with an on-board VIP computer system. All radionuclide scans were obtained with a high-sensitivity slant-hole collimator used to obtain 30 degrees of cephalic angulation for the modified left anterior oblique view. Scans were obtained by use of a 64 × 64 matrix with a full-field view (250 cm). Thirty-two frames per RR interval were acquired to a total of 10 million counts with an acquisition time of 5 to 8 min per view.

Left and right ventricular ejection fractions were subsequently determined from each modified left anterior oblique view. 8

**Serial M mode echocardiography/phonocardiography/Doppler studies.** Serial M mode echocardiography was obtained in each patient 24 hr before and 48 hr after combined valvuloplasty/angioplasty, with an ATL Mark 600 echocardiograph. Aortic valve excursion was measured as the maximal separation between the aortic cusps in systole with use of an inner edge–to–inner edge technique.

Serial systolic time intervals were also obtained in each patient at the time of their echocardiographic study with an Irex System II M mode echocardiograph equipped with capability for phonocardiographic and pulse-tracing studies. The time to one-half carotid upstroke was measured as the time (msec) from the initial rapid upstroke of the carotid pulse to the point at which it had attained one-half its peak amplitude. The left ventricular ejection time was measured as the time (sec) from the initial rapid upstroke of the carotid pulse to the trough of the dicrotic notch, with appropriate correction made for heart rate.

Doppler assessment of aortic insufficiency and mitral regurgitation was determined before and after the procedure with the ATL equipment. Aortic insufficiency was graded simply as either present or absent; in a patient in whom aortic insufficiency was present before valvuloplasty, this technique could not be used to accurately quantify increases in the magnitude of aortic regurgitation that were caused by the valvuloplasty. Mitral regurgitation was classified as absent, mild, moderate, or severe, depending on the extension of the signal of mitral regurgitation from the mitral leaflets to the back wall of the left atrium. 8

**Statistics.** Means and standard deviations were calculated for all variables. Paired t tests were used for determining significant differences between variables before and after combined procedures. A p value less than .05 was considered significant.

**Results**

**Prevalvuloplasty/angioplasty evaluation.** All nine patients had moderate-to-severe aortic valve calcification on fluoroscopy. The peak-to-peak aortic valve gradient was 60 ± 19 mm Hg, with a mean cardiac output of 4.6 ± 0.9 liters/min and a calculated aortic valve area of 0.7 ± 0.1 cm². Left ventricular pressure was elevated at 196 ± 27/20 ± 8 mm Hg, as was pulmonary capillary wedge pressure at 17 ± 10 mm Hg. Left ventricular ejection fraction measured by radionuclide ventriculography averaged 65 ± 12%. Aortic insufficiency was detected by Doppler studies in five of the nine patients. Mitral regurgitation was present in six of the nine patients, including one patient with severe regurgitation, one with moderate regurgitation, and four with mild regurgitation. M mode echocardiography demonstrated thickened aortic valves in all patients with a diminished aortic valve excursion (0.5 ± 0.2 cm). Systolic time intervals demonstrated prolonged time to one-half carotid upstroke (60 ± 20 msec) and a prolonged left ventricular ejection time (0.43 ± 0.04 sec).

Coronary angiography revealed the presence of single-vessel coronary artery disease in all nine patients, including three patients with a stenosis in the left anterior descending artery, three patients with a stenosis in the left circumflex artery, two patients with a stenosis in the right coronary artery, and one patient with a stenosis in a graft to the right coronary artery. The right coronary artery was dominant in seven of the nine patients; the left coronary artery was dominant in two of the three patients with circumflex stenoses. In the four patients with a history of a myocardial infarction, the coronary stenosis was located in the distribution of the previous infarction. In the two patients with prior coronary artery bypass surgery, bypass grafts were patent in one patient and a new stenosis had developed in the native circulation, whereas in the second patient a graft stenosis had developed without progression of disease in the native circulation.

**Angioplasty results.** Angioplasty was accomplished successfully in all nine patients with 2.0 to 3.5 mm balloons. The largest angioplasty balloon used was a 2.0 mm balloon in two patients, a 2.5 mm balloon in two patients, a 3.0 mm balloon in three patients, and a 3.5 mm balloon in two patients. A single stenosis was dilated in all patients with a mean change in percent stenosis from 91 ± 4% to 29 ± 8%. Moderate dissection was noted at the site of the dilatation in three of the nine patients but did not interfere with antegrade flow. Angiographic findings before and after angioplasty are summarized in table 2.
TABLE 2
Coronary angiographic findings before and after angioplasty

<table>
<thead>
<tr>
<th>Patient</th>
<th>Stenosis location</th>
<th>% Obstruction</th>
<th>Balloon sizes used (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RCA</td>
<td>95</td>
<td>2.0, 3.5</td>
</tr>
<tr>
<td>2</td>
<td>LAD</td>
<td>90</td>
<td>2.0, 2.5</td>
</tr>
<tr>
<td>3</td>
<td>RCA</td>
<td>90</td>
<td>2.0, 3.0</td>
</tr>
<tr>
<td>4</td>
<td>CFX</td>
<td>80</td>
<td>2.0</td>
</tr>
<tr>
<td>5</td>
<td>LAD</td>
<td>90</td>
<td>2.0</td>
</tr>
<tr>
<td>6</td>
<td>RCA graft</td>
<td>95</td>
<td>3.0</td>
</tr>
<tr>
<td>7</td>
<td>LAD</td>
<td>90</td>
<td>3.0</td>
</tr>
<tr>
<td>8</td>
<td>CFX</td>
<td>90</td>
<td>2.5</td>
</tr>
<tr>
<td>9</td>
<td>CFX</td>
<td>85</td>
<td>3.0, 3.5</td>
</tr>
</tbody>
</table>

CFX = circumflex artery; LAD = left anterior descending artery; RCA = right coronary artery; RCA graft = graft to right coronary artery.

Valvuloplasty results. Successful aortic valve dilatation was accomplished as evidenced by a significant fall in peak aortic gradient in all nine patients with 20 to 23 mm valvuloplasty catheters. In seven patients a single 20 mm balloon was used, and two patients underwent additional dilatations with a 23 mm balloon. After valvuloplasty there was improvement in peak aortic gradient (60 ± 19 to 33 ± 13 mm Hg; p ≤ .01), aortic valve area (0.7 ± 0.1 to 1.1 ± 0.3 cm²; p ≤ .01), and left ventricular systolic pressure (196 ± 27 to 178 ± 9 mm Hg; p ≤ .01). There was no significant difference after valvuloplasty in cardiac output (4.6 ± 0.9 to 5.3 ± 1.5 liters/min; p = NS), left ventricular diastolic pressure (20 ± 8 to 18 ± 5 mm Hg; p = NS), or pulmonary capillary wedge pressure (17 ± 10 to 16 ± 5 mm Hg; p = NS). Hemodynamic findings before and after valvuloplasty are listed in table 3.

TABLE 3
Hemodynamic findings before and after valvuloplasty

<table>
<thead>
<tr>
<th>Patient</th>
<th>Ao grad (mm Hg)</th>
<th>CO (l/min)</th>
<th>AVA (cm²)</th>
<th>LVEF (%)</th>
<th>Balloon size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
</tr>
<tr>
<td>1</td>
<td>63</td>
<td>48</td>
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</tr>
<tr>
<td>2</td>
<td>84</td>
<td>52</td>
<td>4.2</td>
<td>4.1</td>
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<tr>
<td>3</td>
<td>36</td>
<td>18</td>
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<td>3.2</td>
<td>0.5</td>
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<tr>
<td>4</td>
<td>56</td>
<td>27</td>
<td>5.4</td>
<td>7.1</td>
<td>0.7</td>
</tr>
<tr>
<td>5</td>
<td>62</td>
<td>22</td>
<td>5.1</td>
<td>5.9</td>
<td>0.7</td>
</tr>
<tr>
<td>6</td>
<td>30</td>
<td>18</td>
<td>3.0</td>
<td>3.6</td>
<td>0.8</td>
</tr>
<tr>
<td>7</td>
<td>51</td>
<td>25</td>
<td>4.4</td>
<td>5.9</td>
<td>0.7</td>
</tr>
<tr>
<td>8</td>
<td>66</td>
<td>37</td>
<td>5.8</td>
<td>5.7</td>
<td>0.6</td>
</tr>
<tr>
<td>9</td>
<td>88</td>
<td>46</td>
<td>4.8</td>
<td>4.3</td>
<td>0.6</td>
</tr>
<tr>
<td>Mean</td>
<td>60</td>
<td>33</td>
<td>4.6</td>
<td>5.3</td>
<td>0.7</td>
</tr>
<tr>
<td>SD</td>
<td>19</td>
<td>13</td>
<td>0.9</td>
<td>1.5</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Ao grad = peak-to-peak aortic gradient; AVA = aortic valve area; CO = cardiac output; LVEF = radionuclide left ventricular ejection fraction.

Balloon size refers to the outer diameter of the inflated valvuloplasty balloon.

^p < .01 vs pre.

Technical factors and complications. Combined procedures were completed with a mean arterial time of 108 min (range 61 to 153 min). Total volume of contrast medium used in coronary angiography averaged 108 ± 49 ml. Coronary angioplasty resulted in transient chest pain in three patients and a transient 10 ± 3 mm Hg increase in mean pulmonary arterial pressure during balloon inflation. Aortic valvuloplasty was accompanied by a transient 40 ± 12 mm Hg decrease in systolic arterial pressure and by a 10 ± 5 mm Hg increase in mean pulmonary arterial pressure during balloon infla-

FIGURE 1. Angiograms of 20 mm (left) and 23 mm (right) valvuloplasty balloons being inflated in the aortic valve of a man with critical aortic stenosis. Valvuloplasty resulted in an increase in aortic valve area from 0.8 to 1.1 cm².

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tion, followed by return of these pressures to baseline immediately after inflation. All patients experienced runs of ventricular tachycardia during valvuloplasty balloon inflation, but no patient required cardioversion. No procedure was complicated by embolic phenomenon, hemodynamic evidence of acute aortic insufficiency, prolonged chest pain, or evidence of myocardial infarction. One patient developed a transient left bundle branch block, which disappeared 12 hr after the procedure. A second patient developed atrial fibrillation during aortic valve dilatation, which resolved spontaneously within 3 hr. Two patients developed moderate groin hematomas at the site of arterial puncture and required transfusion.

Figure 1 shows an example of inflated aortic valvuloplasty balloons, and figures 2, 3, and 4 show examples of coronary stenoses before and after angioplasty.

Radionuclide ventriculography. Serial radionuclide ventriculography performed 24 hr before and 48 hr after combined valvuloplasty/angioplasty showed no significant change in left ventricular ejection fraction (65 ±
12% to 65 ± 13%; p = NS) or right ventricular ejection fraction (54 ± 16% to 50 ± 11%; p = NS). It is notable that the only patient (No. 1, tables 1 to 3) with a depressed left ventricular ejection fraction before valvuloplasty demonstrated a significant increase in ejection fraction after the procedure (44% to 53%). It is also notable that one patient (No. 6, tables 1 to 3) with a normal baseline ejection fraction demonstrated a significant decrease in ejection fraction after the procedure (60% to 47%); repeat radionuclide ventriculography 6 weeks after the procedure, however, demonstrated an increase in ejection fraction to 81%.

**M mode echocardiography/systolic time intervals/Doppler studies.** Serial M mode echocardiography performed 24 hr before and 48 hr after combined valvuloplasty/angioplasty showed an increase in aortic valve excursion (0.5 ± 0.2 to 0.9 ± 0.2 cm; p ≤ .01), and a decrease in time to one-half carotid upstroke (60 ± 20 to 50 ± 20 msec; p ≤ .01) and left ventricular ejection time (0.43 ± 0.04 to 0.40 ± 0.03 sec; p ≤ .02). Doppler studies detected no evidence of new aortic insufficiency in four of the patients in whom aortic regurgitation was absent before valvuloplasty. Mitral regurgitation was noted to decrease in four patients after valvuloplasty, including one patient in whom regurgitation decreased from severe to moderate and three patients in whom regurgitation decreased from mild to moderate to absent.

**Clinical follow-up.** One patient (No. 9, tables 1 to 3) who had only a small increase in aortic valve area (0.6 to 0.7 cm²) continued to experience angina after the procedure and eventually elected to undergo surgery. Combined aortic valve replacement and single-vessel bypass grafting were successfully performed and her condition subsequently improved.

The remaining eight patients all noted major improvement in symptoms of angina, dyspnea on exertion, and weakness and were discharged from the hospital. One patient (No.1, tables 1 to 3) noted recurrent symptoms of angina and heart failure 4 months after the procedure. Repeat cardiac catheterization demonstrated restenosis of both her aortic valve and her right coronary artery, and the patient elected to undergo surgery, which was performed successfully. The remaining patients have all done well without recurrent symptoms. At a mean follow-up of 6 months (range 2 to 9), six patients are totally asymptomatic and one patient still experiences mild, infrequent angina.

**Discussion**

This study demonstrates that combined percutaneous coronary angioplasty and balloon aortic valvuloplasty can be carried out safely in adult patients with both critical aortic stenosis and single-vessel coronary artery disease. Successful reduction of coronary stenoses to less than 50% was achieved in all patients, and significant improvement in aortic valve area was achieved in eight of the nine patients. Combined artery and valve dilatation in this study group have thus far resulted in short-term palliation of symptoms of angina and congestive heart failure in a majority of patients.

**A nonsurgical alternative for high-risk patients.** Improvements in intraoperative methods of myocardial preservation as well as advancements in preoperative and postoperative management have significantly decreased the operative risk of aortic valve replacement.
in the last two decades. Recent studies cite a mortality of 1% in patients under 70 years of age with isolated aortic stenosis who undergo elective surgery. Increases in surgical risk, however, have been documented in elderly patients, in patients with coronary artery disease requiring bypass grafting, in patients with congestive heart failure, and in patients with associated medical conditions, including renal insufficiency, pulmonary dysfunction, and malignancy.

As a possible nonsurgical alternative, aortic valvuloplasty has recently been documented as a new modality for treating high-risk surgical patients with critical aortic stenosis. The procedure has been shown to produce at least short-term hemodynamic improvement, including improvement in cardiac output, left ventricular filling pressures, and left ventricular ejection fraction. The long-term effect and overall utility of valvuloplasty, however, are currently being determined. Preliminary reports suggest at least favorable palliation of symptoms 6 months after valve dilatation.

Over the last decade, percutaneous coronary angioplasty has likewise become accepted as an alternative nonsurgical mode of therapy for coronary artery disease. Elderly patients, in particular, represent a subgroup in whom the risk of surgery is higher and in whom a less invasive procedure is attractive. Several large studies have documented the safety and clinical efficacy of coronary angioplasty in elderly patients.

Given the existence of a high-risk surgical population, the proven efficacy of coronary angioplasty in elderly patients, and the promising early results of valvuloplasty studies, it is possible that combined valvuloplasty/angioplasty procedures will be an effective palliative technique for treating selected patients deferred from surgery. A true assessment of the utility of the technique will require a large clinical trial comparing surgery to valvuloplasty/angioplasty and will need to address the actual incidence of coronary and valvular restenosis.

**Interpretation of aortic valvuloplasty results.** The hemodynamic results after aortic valvuloplasty that are reported for the nine patients in this study group are typical of the heterogeneous results that have been previously reported for this technique. It is notable, for example, that three of the nine patients demonstrated only small increases in aortic valve area (patients 2, 3, and 9, tables 1 to 3), whereas the remaining six patients demonstrated postdilation valve areas greater than or equal to 1.0 cm². Similar heterogeneous results are also evident in terms of cardiac output and left ventricular ejection fraction (table 3).

Although it is clear that these heterogeneous results at present impair our ability to define a “successful aortic valvuloplasty,” several important points need to be emphasized based on larger series of preliminary aortic valvuloplasty results. First, postmortem work from our laboratory has indicated that there are several mechanisms of aortic valvuloplasty, including fracture of calcific modules within valve leaflets, separation of fused commissures, and simple stretching of valve leaflets. Given variations in the underlying valvular disease (i.e., senile degenerative aortic stenosis, bicuspid aortic stenosis, rheumatic aortic stenosis) and possible differences in the mechanism of balloon dilatation in different patients, it seems reasonable that there should be a range of valve areas after valvuloplasty. Second, in spite of the heterogeneity of aortic valvuloplasty results, it is clear from several preliminary studies that small increases in aortic valve area have been associated with major improvement in both symptoms and ventricular function, including improvement in cardiac output, left ventricular filling pressures, and left ventricular ejection fraction. Although there was a tendency for improvement in cardiac output and ventricular filling pressures in the present study group, there was no statistical improvement in hemodynamic variables other than aortic valve area and aortic gradient. In part, this may have been related to the fact that baseline ventricular function was well preserved in the study group (i.e., prevalvuloplasty ejection fraction 65%) and that symptoms of angina and heart failure were related to combined aortic stenosis and paroxysmal ischemia secondary to their coronary stenoses. Nevertheless, it is also notable that in five of the nine patients in this study group in whom an aortic valve area greater than 1.0 cm² was achieved after valvuloplasty, all five patients demonstrated significant improvement in cardiac output. And in the one patient in whom left ventricular ejection fraction was depressed before valvuloplasty, ejection fraction increased after the procedure.

**Technical considerations.** In patients undergoing combined valvuloplasty/angioplasty procedures, a major technical consideration is the order in which the aortic and coronary stenoses are dilated. Theoretically, it may be beneficial to perform aortic valvuloplasty before angioplasty to produce a decrease in left ventricular afterload and thereby achieve a global decrease in systolic wall stresses and subendocardial ischemia before attempting dilatation of coronary stenoses. Alternatively, since aortic valvuloplasty is usually accompa-
nied by a transient fall in arterial pressure during balloon inflation and since this hypotension could potentially lead to severe myocardial ischemia in the presence of a critical coronary stenosis and an abrupt increase in left ventricular systolic pressure, it may be argued that angioplasty should precede valvuloplasty. In this study, angioplasty was performed before aortic valve dilatation due largely to technical factors concerning balloon size: angioplasty was performed through a No. 9F sheath, whereas valvuloplasty required femoral arterial dilatation with a No. 12F dilator. To minimize blood loss during the procedure, we began with the procedure requiring the smaller sheath. If technical improvements in the manufacture of valvuloplasty catheters result in smaller-profile balloon catheters capable of insertion through smaller sheaths, it will be possible to assess in a prospective fashion the preferred order of valve/artery dilatation.

A major technical factor related to aortic valvuloplasty that at present is unknown is the maximum diameter of valvuloplasty balloon that can safely be used to dilate an aortic valve. Postmortem work from our laboratory has suggested that a 20 mm balloon could successfully dilate most specimens without damage to the aortic ring or aortic leaflets but that overdistension of the aortic anulus with a 25 mm balloon could result in leaflet avulsion. To date, the maximum balloon size that has been used clinically in our laboratory has been 23 mm; this balloon has been used only if the 20 mm balloon was undersized for the patient, as evidenced by excessive motion of the inflated balloon in the aortic valve and minimal fall in arterial blood pressure during balloon inflation. It is for this reason that 23 mm balloons were not used in some patients in the present study in spite of high residual postvalvuloplasty aortic gradients.

Although angioplasty/valvuloplasty procedures reported in this study were performed as a single procedure, it is also possible that continued investigation will indicate that these two procedures should be performed separately as staged procedures. Of note, although no major angioplasty complications occurred in this study, one can speculate about the hemodynamic tolerance of an angioplasty complication in the setting of aortic stenosis. In particular, an angioplasty complication may be better tolerated after the patient has recovered from a successful aortic valvuloplasty procedure. A staged approach with valvuloplasty first may also provide an opportunity to evaluate the significance of coexistent coronary artery disease and the need for subsequent angioplasty intervention.

Study limitations. Several limitations of this study are notable. First, the study group is small and the combined angioplasty/valvuloplasty approach that was chosen for this group may not be applicable for the majority of patients with combined aortic stenosis and coronary artery disease. Of note, of the 120 consecutive patients that have undergone aortic valvuloplasty at our hospital, over one-third had coexistent coronary disease. The nine patients in the present study were chosen from this larger group of patients because they had only single-vessel coronary artery disease, their coronary lesions were suitable for angioplasty, and angina was a major complaint. The remaining patients were not treated with angioplasty because their coronary disease was too extensive (i.e., multivessel or left main disease) and/or angina was not a major complaint; in these patients, aortic valvuloplasty was performed alone and coronary disease was treated with medical therapy.

A second reason why this study may not be generally applicable to the treatment of patients with combined aortic stenosis and coronary artery disease is because of the potential complications associated both with angioplasty and valvuloplasty. With respect to angioplasty, although several studies have confirmed the efficacy of this procedure in elderly patients, it should be noted that when complications occur in this subgroup of patients the consequences are usually more severe, with a higher mortality in elderly patients compared with younger patients. Similarly, although no major valvuloplasty complications occurred in this study group, all preliminary studies on this technique have reported major life-threatening complications. Only with continued investigation will the safety and overall efficacy of aortic valvuloplasty be established.

Conclusions. Combined balloon aortic valvuloplasty and coronary angioplasty was performed in nine patients with calcific aortic stenosis and coronary artery disease. Reduction of coronary stenoses to less than 50% was achieved in all nine patients, whereas significant improvement in aortic valve area was achieved in eight patients, with postvalvuloplasty aortic valve areas greater than or equal to 1.0 cm² in six. All nine patients were elderly (eight were over 70 years of age), had prominent angina as well as congestive heart failure, and would have had an increased predicted operative mortality based on recent surgical reports. Results of follow-up averaging 6 months are encouraging, although one patient developed both aortic valve and coronary restenosis at 4 months and underwent late aortic valve replacement and coronary artery bypass surgery. Although still experimental, combined aortic valvuloplasty/coronary angioplasty shows promise as a palliative treatment for elderly...
patients with severe aortic stenosis and coronary artery disease.

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Combined percutaneous aortic valvuloplasty and transluminal coronary angioplasty in adult patients with calcific aortic stenosis and coronary artery disease.


Circulation. 1987;76:1298-1306
doi: 10.1161/01.CIR.76.6.1298

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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