Three-Year Outcome After Balloon Aortic Valvuloplasty
Insights Into Prognosis of Valvular Aortic Stenosis

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Background To identify predictors of long-term outcome after balloon aortic valvuloplasty, we analyzed data on 674 adults (mean age, 78±7 years; 56% were women) undergoing this procedure at 24 clinical centers who had a mean initial increase in aortic valve area of 0.3 cm².

Methods and Results Baseline data included clinical, echocardiographic, and catheterization variables. Follow-up data included mortality, cause of death, rehospitalization, 6-month echocardiography, and functional status. Kaplan-Meier curves and log-rank tests were used to evaluate survival in subgroups. Multivariate Cox regression models were used to identify independent predictors of survival. Overall survival was 55% at 1 year, 35% at 2 years, and 23% at 3 years, with the majority of deaths (70%) classified as cardiac by an independent review committee. Rehospitalization was common (64%), although 61% of survivors at 2 years reported improved symptoms. Echocardiography at 6 months (n=115) showed restenosis from the postprocedural valve area of 0.78±0.31 cm² to 0.65±0.25 cm² (P<.0001). With stepwise multivariate analysis, sequentially adding clinical, echocardiographic, and catheterization variables, the overall model identified independent predictors of survival as baseline functional status, baseline cardiac output, renal function, cachexia, female gender, left ventricular systolic function, and mitral regurgitation. Baseline and postprocedural variables were examined to identify which subgroup of patients has the best outcome after aortic valvuloplasty. A "lower-risk" subgroup (28% of the study population), defined by normal left ventricular systolic function and mild clinical functional limitation, had a 3-year survival of 36% compared with 17% in the remainder of the study group.

Conclusions Long-term survival after balloon aortic valvuloplasty is poor with 1- and 3-year survival rates of 55% and 23%, respectively. Although survivors report fewer symptoms, early restenosis and recurrent hospitalization are common.

Key Words • mortality • valves • heart disease • echocardiography • stenoses

Percutaneous balloon aortic valvuloplasty has been proposed as a therapeutic option in adults with severe symptomatic valvular aortic stenosis, especially in patients with a high surgical risk because of comorbid conditions or advanced age.1-14 Immediate postprocedural hemodynamic evaluation has consistently demonstrated a modest but statistically significant decrease in the severity of aortic outflow obstruction, with a majority of patients reporting symptomatic improvement. However, the in-hospital complication rate of this procedure is approximately 30%, and although procedural mortality is only about 3%, 30-day mortality is substantial at 14%.15

Several studies in which sequential catheterization or echocardiographic data were obtained after valvuloplasty have suggested that restenosis occurs, often within a few weeks of the procedure.1,5,6,16-18 Only limited data on outcome beyond 1 year after balloon aortic valvuloplasty have been reported.14

We report the 3-year outcome in the 674 patients who underwent initial balloon aortic valvuloplasty between November 1, 1987, and October 31, 1989, at 24 centers participating in the National Heart, Lung, and Blood Institute Balloon Valvuloplasty Registry.

Methods

Patient Population

Patient enrollment, baseline data collection, procedural details, immediate hemodynamic results, procedural morbidity, and 30-day mortality have been reported previously.13 The committee on human research at each institution approved the research protocol, and all subjects gave informed consent. The age range of the 674 patients was 24 to 103 years, with a mean age of 78±7 years; 83% were >70 years of age, and 56% were women. The initial change in aortic valve area was from 0.5±0.2 to 0.8±0.3 cm²; the change in mean gradient was from 55±21 to 29±13 mm Hg; and the change in cardiac output was from 4.0±1.2 to 4.1±1.1 L/min (P<.0001 for all).15

Follow-up

Scheduled follow-up included telephone contact at 5 weeks and at 6-month intervals after valvuloplasty. Data collection included health status, symptoms, medications, interim hospitalizations, and functional status evaluated with a structured questionnaire.15 The functional status score has a range from 0 to 100 and is calculated from nine specific questions. A score

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of 75 to 100 indicates minimal functional limitation, 50 to 75 indicates moderate functional limitation, and <50 indicates severe functional limitation.

Repeat echocardiography was requested 6 months after valvuloplasty unless the patient had died, had an incomplete procedure, or had aortic valve surgery; however, it was performed at the clinical site for only 209 of 414 patients (50%). Patients with a 6-month echocardiogram did not differ from those without a 6-month echocardiogram in age, gender, functional status, or severity of aortic stenosis at baseline or immediately after valvuloplasty. Echocardiographic data collection included Doppler mean transaortic pressure gradient, continuity equation valve area, severity of aortic regurgitation, and left ventricular systolic function.

Mortality was classified as cardiac, noncardiac, or unknown in cause. Subclassification for cause of cardiac deaths included congestive heart failure, cardiogenic shock, myocardial infarction, sudden cardiac death, or unknown. Classification was made by an outside review committee based on the narrative description, hospital discharge summary, and autopsy results (if available).

At 2 years after the procedure, 90% of patients either were known to be dead or had a follow-up interview. Follow-up at 3 years is complete in 94% of the 413 patients who reached the 3-year postprocedural anniversary. The average follow-up interval was 18±15 months.

Statistical Analysis

Descriptive statistics are used to report symptomatic outcome at each 6-month (±3 month window) follow-up interval. Categorical data are expressed as number plus percentage, and continuous values are expressed as mean±1 SD. Results were censored at the time of aortic valve surgery or repeat valvuloplasty. Changes in echocardiographic data were analyzed only in patients with known values at baseline, after the procedure, and at 6-month follow-up. The paired t test was used to compare measures of stenosis severity, and the Wilcoxon sign-rank test was used to assess changes in aortic regurgitation severity.

Kaplan-Meier curves and log-rank tests were used to evaluate both overall survival and survival in subgroups defined by baseline clinical, echocardiographic, or hemodynamic variables, as well as changes in stenosis severity after valvuloplasty. All survival analyses were censored at the time of aortic surgery. A value of P≤.05 was considered significant.

To identify independent predictors of survival, multivariate Cox regression models were used. First, baseline clinical, noninvasive echocardiographic, and invasive data were considered in separate stepwise analyses. Then, variables that were significant at the P≤.05 level in these three models were considered in the overall model, starting with clinical data and adding echocardiographic and invasive variables in a stepwise regression. This approach was chosen because the clinician usually acquires these data sequentially in an individual patient.

In constructing the model using invasive data, it became clear that one patient with a very large change in aortic valve area (0.6 to 3.4 cm²) and a long survival time (censored at 1280 days) strongly influenced the relation between change in valve area and survival. Change in valve area entered the model if this value was included, but it was nonsignificant without this value. Because it is unlikely that the postprocedural valve area is correct, this patient was excluded from analysis of catheterization variables.

Results

Overall Survival

Patient survival after valvuloplasty was 55% at 1 year (95% confidence limits, 51% to 59%), 35% at 2 years (31% to 39%), and 23% at 3 years (19% to 27%) (Fig 1). The majority of deaths were cardiac in cause (70%) (Table 1).

Postvalvuloplasty Events

There was a high rate of recurrent hospitalization after valvuloplasty (358 of 563 patients, or 64%), with 32% of these patients having three or more subsequent hospitalizations. The reasons for hospitalization are indicated in Table 2. Repeat cardiac catheterization was performed in only 24% of patients, and repeat balloon aortic valvuloplasty was performed in 15% of patients.

Aortic valve surgery subsequently was performed in 134 patients (20%) with valve replacement in all except 5 of these patients (who underwent surgical decalcification procedures (Fig 2). In the patients who underwent aortic valve surgery (at a mean interval of 10±10 days [range, 0 to 41 months] after valvuloplasty), 30-day survival after valve replacement was 88%, and 2-year survival was 71%. Patients undergoing valve surgery were slightly younger (75±8 versus 79±9 years, P=.0001), had a higher cardiac output (4.3±1.1 versus 3.9±1.2 L/min, P=.002), and had better functional status (55±26 versus 45±26, P=.0001).

<table>
<thead>
<tr>
<th>TABLE 1. Classification of Deaths After Balloon Aortic Valvuloplasty</th>
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<tr>
<td><strong>Classification</strong></td>
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<tr>
<td>Cardiac</td>
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<tr>
<td>Congestive heart failure</td>
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<tr>
<td>Cardiogenic shock</td>
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<td>Myocardial infarction</td>
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<tr>
<td>Sudden cardiac death (&lt;1 h, witnessed)</td>
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<tr>
<td>Unwitnessed, presumed sudden cardiac death</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Noncardiac</td>
</tr>
<tr>
<td>Cerebrovascular accident with residual (&gt;24 h)</td>
</tr>
<tr>
<td>Renal failure</td>
</tr>
<tr>
<td>Other</td>
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<tr>
<td>Undetermined</td>
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but they did not differ from the remainder of the study population with respect to aortic valve area, gender, or left ventricular systolic function. This comparison may be biased by severely ill patients who did not survive to have valve surgery.

Symptomatic Outcome
Survivors reported an improvement in symptoms after valvuloplasty based on New York Heart Association (NYHA) functional class or health status (Fig 3). This symptomatic improvement persisted at 3-year follow-up. Functional status score was $47 \pm 27$ at baseline, $58 \pm 30$ at 5 weeks, $63 \pm 29$ at 6 months, and $57 \pm 31$ at 3-year follow-up in the survivors. However, of the 674 enrolled subjects, only 78 (11%) were alive and in NYHA class I or II at 2-year follow-up. The percentage of patients reporting any limitation of activity did not change from before the procedure (79%) to after the procedure (76%) or at longer follow-up (73% at 3 years). Identification of baseline characteristics that predict symptomatic improvement may be biased by the high mortality rate. Even so, no predictors could be identified at 1 year, and the only multivariate predictor of improved symptoms at 2 years was a higher baseline functional status.

Echocardiographic Data
In the 187 patients with baseline, postvalvuloplasty, and 6-month echocardiograms, there was an initial modest decrease in mean pressure gradient and aortic jet velocity and an increase in valve area. However, by 6 months, the pressure gradient had increased and the valve area had decreased to values midway between baseline and postvalvuloplasty measurements (Table 3). From baseline to 6 months, the severity of aortic regurgitation increased slightly overall and changed from 0 to 1+ to values of 2 to 3+ in 15% of patients.

Baseline Predictors of Outcome
Univariate life-table analysis shows that baseline factors related to survival in patients undergoing balloon aortic valvuloplasty include (1) measures of aortic stenosis severity (Doppler aortic jet velocity or catheterization mean transaortic pressure gradient) (Fig 4); (2) left ventricular systolic function evaluated qualitatively by two-dimensional echocardiography as normal or mildly, moderately, or severely reduced (Fig 5); and (3) severity of symptoms as defined by NYHA class or functional limitation as defined by the functional status score (Fig 5). Both mean transaortic pressure gradient and aortic jet velocity were directly related to survival; that is, patients with a higher gradient or jet velocity had a higher survival rate. Other significant variables were mitral regurgitation severity as assessed by Doppler echocardiography ($P<.0001$), renal function ($P<.0001$), and the presence of cachexia ($P<.0001$). There was no significant relation between survival after valvuloplasty and age, hepatic disease, hypertension, diabetes, cerebrovascular disease, dementia, chronic obstructive lung disease, peripheral vascular disease, or neoplasm.

Effect of the Procedure
To assess the impact of the valvuloplasty procedure on survival, both univariate Cox models and multivariate analysis were used, including baseline values, postprocedural values, and change in valve area, valve gradient, and cardiac output from before to after balloon aortic valvuloplasty. Postprocedural values did not have any predictive power after adjusting for preprocedural values. The changes from before to after valvuloplasty in valve area ($P=.04$), valve gradient ($P=.0001$),

![Flow chart of outcome in the 674 patients enrolled in the balloon aortic valvuloplasty (BAV) registry. Percentages are based on the number of patients in that subgroup (denominator) divided by the number of patients in the immediately preceding box (numerator). AVR indicates aortic valve replacement; F/U, follow-up; NYHA, New York Heart Association.](http://circ.ahajournals.org/lookup/suppl/doi:10.1161/01.CIR.89.2.644/-/DC1/12210510507009946.png)
and cardiac output ($P=.05$) were significant univariate predictors of survival but were not significant on multivariate analysis.

**Lower-Risk Subgroup**

In the patients undergoing balloon aortic valvuloplasty for valvular aortic stenosis who had normal or only mildly reduced left ventricular systolic function and a functional status score $>50$, outcome was relatively good with 1-, 2-, and 3-year survival rates of 76% (95% confidence limits, 69% to 82%), 53% (45% to 61%), and 36% (26% to 45%), respectively. In patients undergoing valvuloplasty for aortic stenosis who had moderately reduced left ventricular systolic function and/or a functional status score $\leq 50$, 1-, 2-, and 3-year survival rates were 47% (42% to 52%), 28% (23% to 32%), and 17% (12% to 21%) (Fig 5).

**Multivariate Analysis**

Clinical predictors of survival were functional status, renal function, cachexia, and female gender; echocardiographic predictors were mitral regurgitation severity and left ventricular systolic function; and catheterization predictors were baseline cardiac output and baseline mean gradient.

For the overall model ($P<.0001$), predictors of outcome were functional status ($P<.0001$), left ventricular systolic function ($P=.01$), cardiac output ($P=.0003$), cachexia ($P=0.03$), renal function ($P=.01$), mitral regurgitation ($P=.01$), and female gender ($P=.02$).

**Discussion**

**Overall Mortality**

The 674 subjects in the Balloon Valvuloplasty Registry represent the largest reported series of adults undergoing balloon aortic valvuloplasty. Previous studies, with mean follow-up intervals ranging from 6 to 12 months, have reported 1-year actuarial mortality rates of 35% to 40%. The current data confirm this high 1-year mortality rate (45%) in these elderly, high-risk patients and provide an extended duration of follow-up to 3 years, at which time cumulative mortality is 77%. The major limitation of this registry is that it was not a randomized clinical trial. The absence of a control group in this registry, and in all previous reported series, limits our ability to draw definite conclusions as
Differences in baseline variables between the two populations cannot be excluded, although group mean ages are similar, and in both groups, valve replacement was deferred for a variety of reasons. The absence of a dramatic difference in survival between patients undergoing valvuloplasty and those with no intervention suggests that the survival curves after balloon aortic valvuloplasty to a great extent reflect the natural history of the underlying disease and are either unrelated or only mildly related to the procedure itself.

In contrast, although aortic valve replacement in the elderly carries a higher surgical mortality (range, 8% to 29%) and morbidity than in younger patients, in several series elderly patients undergoing aortic valve replacement for aortic stenosis had 1-year survival rates of 65% to 85%. In the present registry, the subgroup of patients (20%) who underwent valve replacement after valvuloplasty had a 1-year survival of 78%. It is likely that these patients represent a lower risk group.

Clinical Outcome After Valvuloplasty

Patients surviving valvuloplasty report improved health status, fewer symptoms, and a modest increase in functional status score. The only identifiable baseline predictor of symptomatic improvement in survivors was functional status score. The rate of recurrent (and repeated) hospitalization was high, and nearly one third of survivors underwent repeat valvuloplasty or subsequent aortic valve replacement for persistent severe symptomatic stenosis. Possibly, those who reported symptomatic improvement had improved diastolic ventricular function, which was not assessed in the present study.

In the subset of patients with 6-month echocardiographic studies, restenosis was evident, with a significant decrease in valve area and increase in mean transaortic pressure gradient. These observations are similar to those reported in smaller numbers of subjects. Potential selection biases in this subset cannot be excluded, although no differences between this subset and the remainder of the study population were found for a wide range of baseline variables. If anything, this subset may underestimate restenosis because patients who died or underwent valve replacement within the first 6 months are not included.

Predictors of Outcome

Potential predictors of outcome in elderly adults undergoing balloon aortic valvuloplasty were evaluated in a stepwise manner analogous to the sequence in which these data would be available to the clinician when caring for an individual patient. It is noteworthy that knowledge of a single clinical variable (eg, functional status score) or of simple noninvasive echocardiographic data (eg, left ventricular systolic function or aortic jet maximum velocity) provides important prognostic information. For example, if left ventricular systolic function on two-dimensional echocardiography is described qualitatively as "normal" or "mildly reduced," 1-year survival in 59% to 69% compared with 26% to 50% for "moderately" or "severely reduced" left ventricular systolic function. Multivariate analysis indicates that the most important factors affecting survival are baseline functional status, renal function, female gender, mitral regurgitation severity, baseline cardiac output, cachexia, and left ventricular systolic function. Because multivariate analysis may select only one of several related baseline variables, these findings should not be overinterpreted. The explanation for gender being a multivariate predictor of survival in severe aortic stenosis is complex. Gender is a univariate predictor of survival only in the subgroup with a low cardiac output (<3.0 L/min). In addition, the direction of the effect was opposite (women had better survival) that found in other studies of cardiovascular disease.

Effect of the Valvuloplasty Procedure

The effect of the valvuloplasty procedure on mortality is difficult to assess given the absence of a control group. The hemodynamic changes reported for the present series and by others consistently show highly statistically significant but hemodynamically modest decreases in pressure gradient and increases in valve area after balloon valvuloplasty. Most patients...
have severe (albeit slightly less severe) aortic stenosis after the valvuloplasty procedure. Many investigators believe that valvuloplasty may be helpful as a "bridge" to surgery in critically ill patients (7% of the present series) or as an alternative to valve replacement in patients with severe aortic stenosis requiring emergency noncardiac surgery.\textsuperscript{37,38} It is difficult to compare the subgroup who had subsequent valve replacement with other series of elderly patients undergoing aortic valve replacement because of differences in study selection criteria. Only a controlled, randomized trial would directly address the potential impact of valvuloplasty on survival.

**Lower-Risk Subgroup**

In attempting to identify the subgroup of patients who benefit most from this procedure, we found consistent relations between survival and several measures of generalized debility, including functional status, NYHA class, cachexia, and renal function. In addition, left ventricular function assessed either by echocardiography or as cardiac output was consistently related to survival. Stenosis severity was related to survival in that patients with higher gradients (and better left ventricular function) had a better outcome than did those with low gradients, albeit all subjects had significant aortic valve obstruction. Thus, in patients with severe symptomatic valvular aortic stenosis, the subgroup of patients with the best survival after valvuloplasty were those with minimal functional limitation and normal or mildly reduced left ventricular systolic function. Compared with patients with more functional limitation, depressed left ventricular systolic function, or both, 2-year survival was 53% versus 28%. This observation may be useful in defining the prognosis for individual patients with aortic stenosis in whom surgery is high risk because of coexisting noncardiac disease and in comparing the expected outcome after valve replacement with the expected course of the disease. If the goal is symptomatic improvement over the short term (rather than an improvement in survival), balloon aortic valvuloplasty may be an alternative in selected patients not considered to be surgical candidates.

**Conclusions**

Long-term survival after balloon aortic valvuloplasty is poor. Although survivors reported fewer symptoms,
Fig 5. Upper left, Plot of survival by baseline left ventricular systolic function assessed qualitatively on two-dimensional echocardiography as normal (solid line) or mildly (dashed line), moderately (short dashed line), or severely reduced (dash-dot line) (P<.0001). Upper right, Plot of survival by baseline functional status score of 0 to 25 (solid line), 26 to 50 (dashed line), 51 to 75 (short dashed line), or 75 to 100 (dash-dot line) (P<.0001). Lower left, Plot of survival by the increase in aortic valve area after valvuloplasty of <0.3 cm² (solid line) vs ≥0.3 cm² (dashed line) (P=.5). Lower right, Plot of low-risk subgroup defined as normal or mildly reduced left ventricular systolic function plus a functional status score ≥50 (solid line) vs the remainder of the population (dashed line) (P<.0001).

early restenosis and recurrent hospitalizations were common. Given the similar reported mortality rates for unoperated patients with severe symptomatic aortic stenosis and the absence of convincing data that the procedure affects outcome, it is possible that survival curves after valvuloplasty simply represent the natural history of this disease. Survival is dependent on left ventricular systolic function, aortic stenosis severity, and the degree of functional limitation at baseline.

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Appendix

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University of Washington, Seattle: Catherine M. Otto, MD*†; Douglas K. Stewart, MD.
William Beaumont Hospital, Royal Oak, Mich: William O’Neill, MD*; Andrew Hauser, MD†; Patricia Dudlets, MD; Gregory Paviletes, MD; Connie Gangadharan, RN; Ann Margulis, RN.
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National Heart, Lung, and Blood Institute
National Institutes of Health, Bethesda, Md: George Sopko, MD; Robert A. Julia, Sharon Kraft.

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