Clin. Cardiol. 24, 214–218 (2001)

Efficacy of Balloon Valvuloplasty in Patients with Critical Aortic Stenosis and Cardiogenic Shock—The Role of Shock Duration

ARND B. BUCHWALD, M.D., THOMAS MEYER, M.D., KARLHEINZ SCHOLZ, M.D., BERND SCHORN, M.D.,* CHRISTINA UNTERBERG, M.D.

Departments of Cardiology and *Cardiothoracic Surgery, University Clinic Göttingen, Göttingen, Germany

Summary

Background: Because of limited long-term success, aortic balloon valvuloplasty is considered to be a palliative procedure, including patients at excessive risk for standard therapy—aortic valve replacement—that is, those in cardiogenic shock.

Hypothesis: The study was undertaken to evaluate the outcome of balloon valvuloplasty for critical aortic stenosis complicated by cardiogenic shock.

Methods: Over a 10-year-period, we followed 14 patients (age 74 ± 11 years, range 50–91) presenting in cardiogenic shock and critical aortic stenosis, who underwent valvuloplasty, together with 19 patients with critical aortic stenosis requiring urgent major noncardiac surgery.

Results: In patients in shock, calculated aortic valve area could be increased successfully by at least 0.3 cm^2, from 0.38 ± 0.09 to 0.81 ± 0.12 cm^2, with an insignificant increase in cardiac index from 1.89 ± 0.33 to 2.01 ± 0.41 l/min * m^2. In-hospital mortality was 71% (10 patients). Two patients underwent valve replacement within 16 days and survived after 1 year, as did two patients refusing surgery. By multivariate logistic regression analysis, only an interval between onset of shock symptoms and valvuloplasty of > 48 h was significantly associated with fatal outcome ($p < 0.01$). In those patients requiring noncardiac surgery, this was possible after valvuloplasty in 95% who survived 1 year after hospital discharge. One patient in this group died of pulmonary embolism the day after the procedure.

Conclusion: These data support the concept of causal treatment in patients with cardiogenic shock, as well as in the setting of cardiogenic shock and critical aortic stenosis, at the earliest possible convenience.

Key words: aortic valve stenosis, shock, valvuloplasty

Introduction

Balloon valvuloplasty has become the treatment of choice for most patients with isolated severe mitral valve stenosis. Both acute and long-term results are excellent, with a very low recurrence rate.[1–3] Balloon valvuloplasty for aortic stenosis has initially been shown to improve symptoms effectively in elderly persons.[4,5] However, follow-up studies showed a high restenosis rate, exceeding 70% 1 year after the procedure. Moreover, significant restenosis is already evident in many patients shortly after the procedure.[6–9] Therefore, aortic valve replacement (AVR) remained the only available therapy to influence the poor prognosis of patients presenting with symptomatic aortic stenosis.

Surgical results improved over time, and today AVR can be performed successfully, even in octogenarians, with very acceptable operative risk and long-term outcome.[10,11] A major factor known to affect operative survival negatively is severe left ventricular dysfunction prior to surgery. Patients presenting with decompensated left ventricular function are therefore often not considered to be acceptable candidates for AVR. Here we report on the results of an approach, in which patients with decompensated aortic valve stenosis, requiring inotropic support or mechanical ventilation or both, underwent balloon valvuloplasty and received AVR only after recompensation. Of these patients in shock, those who did and did not survive were compared with stable patients undergoing aortic valvuloplasty prior to surgery for gastrointestinal cancer or active bleeding.

Methods

Patients

Between January 1989 and December 1998, 33 patients underwent balloon aortic valvuloplasty at our center. Fourteen patients (7 women) presented with decompensated aortic

Address for reprints:

Arnd B. Buchwald, M.D.
Zentrum Innere Medizin
Abteilung Kardiologie und Pneumologie
Universitätsklinik
Robert-Koch-Str. 40
37075 Göttingen, Germany

Received: January 14, 2000
Accepted with revision: May 12, 2000

stenosis (Group 1). All showed pulmonary edema on clinical investigation and chest x-ray on admission. Three patients were on mechanical ventilation, four required intravenous inotropic support, and seven needed both. Acute myocardial infarction contributed to decompensation in two patients (of a total of five patients later shown to have concomitant coronary artery disease), but serum creatine kinase peaked at modestly elevated levels of 420 and 560 U/l 24 h after admission. None of the patients had a history of prior myocardial infarction. After confirmation of the clinical diagnosis of aortic stenosis by Doppler echocardiography, a cardiologist and a cardiothoracic surgeon agreed on the decision that both conservative management as well as urgent aortic valve replacement were associated with a very high risk in each case, and the decision to perform aortic valvuloplasty was made.

Duration of shock symptoms was defined as the period between documented onset of heart rate > 100/min and systolic aortic pressure < 90 mmHg, or start of inotropic drugs, or the beginning of mechanical ventilation secondary to documented oliguria and pulmonary edema on chest x-ray. In the 11 patients referred to our center from other hospitals, this could underestimate the true duration of symptoms, since we solely relied on the documents sent to us with the patient.

Nineteen patients (12 women) (Group 2) were referred to our clinic because of gastrointestinal cancer or active bleeding, requiring urgent surgery, but they also had severe aortic stenosis, associated with a history of dyspnea and/or chest pain on mild to moderate exertion in the preceding months. Demographics of the patients are given in Table I.

Valvuloplasty

After right- and left-heart catheterization, aortic valvuloplasty was performed via the femoral retrograde approach. Patients received a bolus of 5,000 U of unfractionated heparin, and an extra stiff exchange wire was placed in the left ventricle. Over this wire, a 4 cm long balloon was introduced with a diameter of 18 to 23 mm, according to the diameter of the aortic root. The primary target was to increase orifice area, but not to relieve any obstruction completely. Hence, larger balloons (25 mm, 3 × 10 mm trifoil) were used only when the calculated valve area had not changed after the initial balloon had been inflated twice for 30 to 60 s.

Statistical Analysis

Results were analyzed with the StatView™ statistics software for windows (Version 4.53, Abacus Concepts, Berkeley, Calif., USA). In general, data are presented as mean ± standard deviation, where indicated median and range are given. Hemodynamic variables before and after valvuloplasty within the groups were compared using the Student's paired *t*-test. The following factors were analyzed by multivariate logistic regression analysis for independent prediction of hospital survival: age, gender, presence of coronary artery disease, baseline and postvalvuloplasty hemodynamics, and duration of shock symptoms before valvuloplasty. Chi-square analysis was used, with a p value < 0.05 considered to indicate significance.

Results

The peak transvalvular gradient could be reduced by 38.7 ± 15.8 mmHg in Group 1 and by 41.8 ± 19.3 mmHg in Group 2. This corresponded to an increase in valve opening area to 0.81 ± 0.12 and 0.89 ± 0.17 cm^2, respectively. Transvalvular gradient was reduced by at least 30 mmHg with the first balloon in 10 patients in Group 1 and in 13 patients in Group 2. Minimal and maximal increase in valve opening area were 0.3 and 0.6 cm^2, respectively. Cardiac index in all patients increased acutely only slightly after the procedure.

Severe aortic insufficiency occurred in two patients, one in each group, requiring urgent aortic valve replacement. Death

TABLE 1 Demographics and hemodynamic values

Group (indication for valvuloplasty)	Group 1(shock)			Group 2 (bleeding /tumor)		
No. of patients	14			19		
Age (years)	74.1 ± 11.4			70.0 ± 8.7		
Range	50–91			53–83		
Coronary artery disease (n)	5			6		
Acute myocardial infarction (n)	2			0		
Patients on mechanical ventilation (n)	8			0		
Patients on catecholamines (n)	11			0		
	Before AVP	After AVP	p Value	Before AVP	After AVP	p Value
Heart rate (1/min)	105 ± 19	110 ± 27	NS	76 ± 14	84 ± 19	NS
Systolic aortic pressure (mmHg)	91 ± 8	92 ± 24	NS	125 ± 29	116 ± 23	NS
Transvalvular pressure gradient (mmHg)	80.0 ± 19.1	41.4 ± 18.8	<0.001	91.6 ± 21.6	50.5 ± 15.5	<0.001
Calculated aortic valve area (cm^2)	0.38 ± 0.09	0.81 ± 0.12	<0.001	0.45 ± 0.11	0.84 ± 0.19	<0.001
Cardiac index (l/min * m^2)	1.89 ± 0.33	2.01 ± 0.41	NS	3.1 ± 0.3	3.3 ± 0.2	NS

Abbreviations: AVP = aortic balloon valvuloplasty, NS = not significant.

within 24 h of valvuloplasty occurred only in four patients (29%) in Group 1, one of whom underwent urgent aortic valve replacement because of severe aortic insufficiency following valvuloplasty.

In Group 1, two patients improved hemodynamically after valvuloplasty and were transferred to valve replacement surgery after 8 and 16 days, respectively, and survived to hospital discharge. One additional patient developed severe aortic insufficiency and was operated on after 16 h, but died 3 weeks later. This results in an AVR rate of 21%.

The condition of 9 of the 11 remaining patients in this group did not improve. They continued to need mechanical ventilation and intravenous inotropic support in increasing or unchanged doses and died within 30 days, accounting for a total in-hospital mortality of 71% (10 of 14 patients). Four patients (29%) were alive after 1 year, including two with AVR and two who refused surgery.

Survival According to Duration of Shock Symptoms before Valvuloplasty

Valvuloplasty could be performed within 24 h (8 to 18 h) in 4 patients, while in 10 patients the procedure was performed between 48 h and 8 days after shock onset. These 10 patients had not been transferred earlier because of the opinion of the referring physician, the patient, or the patient's family that they were either too old or that conservative management could improve the status. All of these 10 patients died before hospital discharge, while the other 4 survived for 1 year. Multivariate logistic regression analysis revealed duration of shock symptoms >48 h as the only independent predictor of fatal outcome ($p < 0.01$).

In contrast, AVR was performed in 16 patients in Group 2 (84%). Of these patients, 95% (all but one) survived to hospital discharge after noncardiac surgery. One-year survival was 84% (16 patients), including 1 patient without and 15 patients with subsequent AVR. Details are given in Tables II and III.

Discussion

Acute cardiac decompensation in patients with aortic stenosis has a very poor prognosis. This report on a 10-year experience in our center shows that, once decompensation has reached the state of cardiogenic shock, aortic balloon valvuloplasty influences fatal outcome only in rare cases, with a hospital mortality rate of 71%. This number is close to mortality rates reported on patients in cardiogenic shocks of different origin, such as acute myocardial infarction.[10, 11] Similar to that condition, duration of shock symptoms before

TABLE II Patients in shock

Number	Age (years)	Gender	AoPSys Pre-AVP (mmHg)	Δ-P pre AVP (mmHg)	Δ-P post AVP (mmHg)	Co-morbid Illness	On catechol-amines	On respirator	Hours in shock
Nonsurvivors									
1	65	F	95	55	25	CAD	Yes	No	72
2	59	M	110	100	70		Yes	Yes	61
3	85	M	75	106	75		Yes	Yes	72
4	50	M	95	35	30		No	Yes	49
5	69	M	90	80	40	CAD	Yes	No	55
6	81	M	95	70	15		Yes	No	72
7	91	F	85	90	70		Yes	Yes	63
8	69	F	80	100	40		Yes	Yes	62
9	77	F	85	90	40		Yes	No	60
10	85	F	90	70	30	CAD, diabetes	No	Yes	52
Mean ± SD	72 ± 12		90 ± 9	80 ± 21	43 ± 20		80%	60%	61.8 ± 8
Survivors									
1	79	F	105	85	20	CAD, diabetes	Yes	No	8
2	75	M	90	70	35	CAD	No	Yes	10
3	68	M	85	90	50		Yes	No	14
4	85	F	90	80	40	Diabetes	Yes	Yes	16
Mean ± SD	77 ± 6[a]		93 ± 8[a]	81 ± 7[a]	36 ± 11[a]		75%	50%	12 ± 3[b]

[a] p = not significant.

[b] $p < 0.01$.

Abbreviations: AoPSys = aortic systolic pressure, AVP = aortic valvuloplasty, F = female, M = male, CAD = coronary artery disease, SD = standard deviation.

TABLE III Outcome

Group (indication for valvuloplasty)	Group 1 (shock) n/(%)	Group 2 (bleeding/tumor) n/(%)
No. of patients	14 (100)	19 (100)
AVR performed	3 (21)	6 (84)
Interval AVP to AVR		
Median range	16 h to 16 days	24 h to 48 months
In-hospital mortality		
Total	10 (71)	1 (5)
+ AVR	1 (7)	0
− AVR	9 (64)	1 (5)
30-Day survival		
Total	5 (36)	18 (95)
+ AVR	2 (14)	16 (84)
− AVR	3 (21)	2 (11)
1-year-survival		
Total	4 (29)	18 (95)
+ AVR	2 (14)	16 (84)
− AVR	2 (14)	2 (11)
Valvuloplasty complications		
Intraproced. death	0	0
Aortic insufficiency requiring acute AVR	1 (7)	1 (5)
Peripheral vascular surgery	3 (21)	3 (16)
Stroke with permanent disability	Not recognized in critically ill patients, partially on mechanical ventilation	1 (5)

Abbreviations: AVP = aortic balloon valvuloplasty, AVR = aortic valve replacement, + = with, − = without.

causal treatment (in this setting relief of valve obstruction) is attempted seems to determine outcome: none of the 10 patients who were in shock for > 48 h survived, whereas the 4 patients treated within 24 h of onset of shock symptoms were discharged from hospital and were alive after 1 year.

Aortic valvuloplasty was attempted in patients to be at extremely high risk for the standard treatment for aortic stenosis, that is, valve replacement. In recent reports, isolated AVR in patients with preserved left ventricular function was shown to have an operative mortality as low as 3–10%. Even in octogenarians this procedure can be performed at an acceptable low risk.[12, 13] However, operative mortality increases with preoperatively depressed ventricular function or concomitant heart disease requiring aortocoronary bypass surgery or mitral valve replacement.[14] In this setting, the decision to perform aortic balloon valvuloplasty as a bridge to definite corrective surgery was made in patients considered to have an operative risk of > 30%.

We found three other reports in the literature on aortic balloon valvuloplasty in the setting of cardiogenic shock that included more than three patients.[15–17] The available data are summarized in Table IV. In-hospital- or 30-day-mortality

TABLE IV Aortic balloon valvuloplasty in patients with cardiogenic shock and critical aortic valve stenosis

Study (Ref. No.)	N	Age (years)	M/F	Mech vent. (n)	Inotr. supp. (n)	AP before (mmHg)	AP after (mmHg)	CI before (l/min*m²)	CI after (l/min*m²)	AVA before (cm²)	AVA after (cm²)	δP before (mmHg)	δP after (mmHg)	In-hosp. death (n)	death < 30 days (n)	AVR (n)	1-Y Surv. (n)
NHLBI (17)	39	*	*	*	*	*	*	*	*	*	*	*	*	*	20 (51%)	*	*
Cribier *et al.* (15)	10	64 ± 9 (54–79)	8/2	?	?	71 ± 8	80 ± 14	1.90 ± 0.34	2.30 ± 0.40	0.47 ± 0.10	0.95 ± 0.30	54 ± 19	28 ± 14	1 (10%)	2 (20%)	6 (60%)	?
Moreno *et al.* (16)	21	74 ± 3 35–90	10/11	?	?	77 ± 3	116 ± 8	1.84 ± 0.13	2.24 ± 0.15	0.48 ± 0.04	0.84 ± 0.06	49 ± 4	21 ± 3	9 (43%)		1 (5%)	7 (33%)
This report	14	74 ± 11 50–91	7/7	8 (57%)	11 (79%)	91 ± 8	93 ± 24	1.89 ± 0.33	2.01 ± 0.41	0.38 ± 0.09	0.81 ± 0.12	49 ± 9	24 ± 11	10 (71%)	8 (67%)	3 (21%)	4 (29%)

* Not detailed in publication (subgroup of large series).

Abbreviations: M/F = male/female, mech. vent. = mechanical ventilation, inotr. supp. = intravenous inotropic drugs, AP = aortic pressure, CI = cardiac index, AVA = aortic valve area, δP = mean valvular pressure gradient, AVR = aortic valve replacement, 1-Y-surv = survival after 1 year.

(whichever was given) varies between 20 and 51% compared with 71% in our series. Hemodynamic data before and after valvuloplasty did not differ much between the studies. A possible explanation for the poor prognosis in our series might be found in the high percentage of patients who were either on mechanical ventilation, intravenous inotropic support, or both. These data were not explicitly indicated in the other reports. A second possible cause for the high early mortality in our series could be the duration of shock symptoms before referral to our center, which was at least 48 h in 10 of the 14 patients.

In Group 2, aortic balloon valvuloplasty was performed to decrease the risk of noncardiac surgery urgently indicated for symptomatic gastrointestinal cancer or active bleeding gastric ulcers. These conditions greatly increase the risk of primary valve surgery because of the necessary anticoagulation for cardiopulmonary bypass, while, on the other hand, primary noncardiac surgery is associated with a significant cardiac risk, approaching 5% for patients in New York Heart Association class 3 because of various underlying diseases.[18]

In this group, significant relief of valve stenosis was achieved by valvuloplasty, allowing subsequent noncardiac surgery und later AVR in all patients but one (95%). The 1-year survival rate of 84% in a group of patients suffering from severe aortic stenosis and nonmetastasing cancer (in 10 of 19 patients) seems very acceptable and is well in accordance with the results of larger previous reports on such an approach.[19,20] This approach of palliative valvuloplasty to allow for early noncardiac surgery might decrease the risk of metastases to occur and improve prognosis and/or quality of life, in addition to decreasing the risk of both cardiac and noncardiac surgery.

Study Limitations

This report is a retrospective, single-center analysis lacking a control group, with the problems inherent in such a design. It is similar to the majority of other studies on the topic of cardiogenic shock, although emphasis was put on detailed evaluation of data. Specifically, the history including exact treatment in the referring hospitals and the patient's potential reluctance to invasive therapy before onset of shock might be less complete. Follow-up is limited to 1 year because of difficulties in collecting information on the whereabouts of patients referred from very distant centers.

Conclusion

Although the number of patients in this series is small, this report extends the findings from previous, similar-sized reports in providing support for a concept of earliest possible causal treatment in cardiogenic shock, including that due to critical aortic stenosis,[21] to improve poor prognosis.

References

1. Turi ZG, Reyes VP, Raju BS, Raju AR, Kumar DN, Rajagopal P, Sathyanarayana PV, Rao DP, Srinath K, Peters P, Connors B, Fromm B, Farkas P, Wynne J: Percutaneous balloon versus surgical closed commissurotomy for mitral stenosis: A prospective randomized trial. *Circulation* 1991;83:1179–1185
2. Patel JJ, Shama D, Mitha AS, Blyth D, Hassen F, LeRoux BT, Chetty S: Balloon valvuloplasty versus closed commissurotomy for pliable mitral stenosis: A prospective hemodynamic study. *J Am Coll Cardiol* 1991;18:1318–1326
3. Ayari M, Farhat MB, Chouaieb A, Maatoug F, Jarrar M, Sghairi K, Fendri A: Two-dimensional echocardiographic and hemodynamic assessment of surgical valvulotomies versus percutaneous balloon mitral commissurotomy. *Eur Heart J* 1991;144:172–180
4. Cribier A, Saoudi N, Berland J, Savin T, Rocha P, Letac B: Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: An alternative to valve replacement? *Lancet* 1986;1:63–67
5. McKay RG, Safian RD, Lock JE, Mandell VS, Thurer RL, Schnitt SJ, Grossman W: Balloon dilatation of calcific aortic stenosis in elderly patients: Postmortem, intraoperative, and percutaneous valvuloplasty studies. *Circulation* 1986;74:119–125
6. Letac B, Cribier A, Eltchaninoff H, Koning R, Derumeaux G: Evaluation of restenosis after balloon dilatation in adult aortic stenosis by repeat catheterization. *Am Heart J* 1988;122:55–60
7. Grollier G, Commeau P, Sesoué B, Huret B, Potier JC, Foucault JP: Short-term clinical and hemodynamic assessment of balloon aortic valvuloplasty in 30 elderly patients: Discrepancy between immediate and eighth-day hemodynamic values. *Eur Heart J* 1988;9:(suppl)155–162
8. Geibel A, Kasper W, Reifart N, Faber T, Just H: Clinical and Doppler echocardiographic follow-up after percutaneous balloon valvuloplasty for aortic valve stenosis. *Am J Cardiol* 1991;67:616–621
9. Otto CM, Mickel MC, Kennedy JW, Aldermann EL, Bashore TM, Block PC, Brinker JA, Diver D, Ferguson J, Holmes DR, Lambrew CT, McKay C, Palacios IF, Powers ER, Rahimtoola SH, Weiner BH, Davis KB: Three-year outcome after balloon aortic valvuloplasty. *Circulation* 1994;89:642–650
10. Califf RM, Bengtson JR: Cardiogenic shock. *N Engl J Med* 1994; 339:1724–1730
11. DeWood MA, Notske RN, Hensley GR, Shields JP, O'Grady WP, Spores J, Goldman M, Ganji JH: Intra-aortic balloon counterpulsation with and without reperfusion for myocardial infarction shock. *Circulation* 1980;61:1105–1112
12. Bergdahl L, Bjork VO, Jonasso R: Aortic valve replacement in patients over 70 years. *Scand J Thorac Cardiovasc Surg* 1981;15: 123–129
13. Santiga JT, Flora J, Kirsh M, Baublis J: Aortic valve replacement in the elderly. *J Am Geriatr Soc* 1983;31:211–215
14. Logeais Y, Langanay T, Roussin R, Leguerrier A, Rioux C, Chaperon J, dePlace C, Mabo P, Pony JC, Daubert JC, Laurent M, Almange C: Surgery for aortic stenosis in elderly patients. *Circulation* 1994;90:2891–2898
15. Cribier A, Remadi F, Koning R, Rath P, Stix G, Letac B: Emergency balloon valvuloplasty as initial treatment of patients with aortic stenosis and cardiogenic shock (letter). *N Engl J Med* 1992;323:646
16. Moreno PR, Jang IK, Newell JB, Block PC, Palacios IF: The role of percutaneous aortic balloon valvuloplasty in patients with cardiogenic shock and critical aortic stenosis. *J Am Coll Cardiol* 1994; 23:1071–1075
17. NHLBI Balloon Valvuloplasty Registry Participants: Percutaneous balloon aortic valvuloplasty: Acute and 30-day follow-up results in 674 patients from the NHLBI Balloon Valvuloplasty Registry. *Circulation* 1991;84:2383–2397
18. Eagle KA, Rihjal S, Mickel MC, Holmes DR, Foster ED, Gersh BJ: Cardiac risk of noncardiac surgery. *Circulation* 1997;96:1882–1887
19. Levine MJ, Bermann AD, Safian RD: Palliation of valvular aortic stenosis by balloon valvuloplasty as preoperative preparation for noncardiac surgery. *Am J Cardiol* 1988;62:1309–1310
20. Roth RB, Palacios IF, Block PC: Percutaneous aortic balloon valvuloplasty: Its role in management of patients with aortic stenosis requiring major noncardiac surgery. *J Am Coll Cardiol* 1989; 13:1039–1041
21. Rahimtoola SH: Catheter balloon valvuloplasty for severe calcific aortic stenosis: A limited role. *J Am Coll Cardiol* 1994;23: 1076–1078