

18 Years Follow-up Results of Mitral Balloon Valvuloplasty in 531 Consecutive Patients and Predictors of Long-Term Outcome

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Abstract

Background: Aim of the study: Long-term echocardiographic follow-up studies of mitral balloon valvuloplasty (MBV) are scarce. The study aim was to assess the long-term results (up to 18 years) of MBV and to identify predictors of restenosis and event-free survival.

Methods: The immediate and long-term clinical and echocardiographic results for 531 consecutive patients (mean age 31 ± 11 years) who underwent successful MBV for severe mitral stenosis (MS) and were followed up for a mean of 8.5 ± 4.8 years (range: 1.5 to 18 years) after MBV are reported.

Results: Immediately after MBV, the mitral valve area (MVA) was increased from 0.92 ± 0.17 cm² to 1.95 ± 0.29 cm² ($p < 0.0001$). Restenosis occurred in 165 patients (31%), and was less frequent (19%) in patients with a low mitral echo score (MES ≤ 8). Actuarial freedom from restenosis at 10, 15 and 18 years was $77 \pm 2\%$, $46 \pm 3\%$ and $18 \pm 4\%$, respectively, and was significantly higher in patients with MES ≤ 8 ($86 \pm 2\%$, $62 \pm 4\%$ and $31 \pm 7\%$) than in those with MES > 8 ($p < 0.001$). Event-free survival (death, redo MBV, mitral valve replacement, NYHA class III or IV) at 10, 15 and 18 years was $88 \pm 1\%$, $53 \pm 4\%$, and $21 \pm 5\%$ respectively, and was significantly higher for patients with MES ≤ 8 ($93 \pm 2\%$, $65 \pm 5\%$ and $38 \pm 8\%$, respectively; $p < 0.001$). Multivariable Cox regression analysis identified MES > 8 ($p < 0.0001$) and previous surgery ($p = 0.043$) as predictors of restenosis, and MES > 8 ($p < 0.0001$) and baseline atrial fibrillation ($p = 0.03$) as predictors of combined events.

Conclusion: MBV provides excellent long-term results for selected patients with MS. The long-term outcome of this procedure can be predicted from the baseline clinical and echocardiographic characteristics of the mitral valve. *Heart Views* 2007;8(4):130-141. © Gulf Heart Association 2007.

Keywords: ? mitral balloon valvuloplasty ? mitral stenosis

Introduction

Mitral balloon valvuloplasty (MBV) is an established non-surgical modality for the treatment of severe rheumatic mitral stenosis (MS). Although numerous studies have documented favourable immediate and intermediate follow-up results¹⁻¹², long-term echocardiographic follow-up studies of MBV are scarce¹³⁻¹⁸. The purpose of this study was to report the long-term (up to 18 years) clinical and echocardiographic results of 531 consecutive patients who underwent successful MBV at a single institution. The analysis of these data allowed identification of factors that influence long-term outcome after MBV. We also analyze the results of MBV in children, patients with persistent atrial fibrillation (AF) at baseline, patients with extreme pulmonary hypertension, and pregnant women.

Methods

Study Population

Between 1989 and 2005, a total of 562 consecutive patients with severe MS underwent MBV as a first procedure at the authors' institution. Patients who had undergone redo MBV were excluded from this study. Patient baseline characteristics are listed in Table 1. On the basis of immediate results, the procedure was successful in 542 patients (96.4%) and unsuccessful in the remaining 20 (3.6%) patients. The failures included nine patients who developed severe mitral regurgitation (MR $\geq 3/4$) and 11 who had a post-procedure mitral valve area (MVA) < 1.5 cm². These 20 patients were excluded from further long-term result analysis.

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Table 1: Baseline characteristics of 562 patients undergoing mitral balloon valvuloplasty

Variables	Value
Age (years)	31 ± 11
Female sex	385
Mitral echo score (MES)	8.0 ± 1.1
? 8	355
> 8	207
Prevalvuloplasty AF	71 (12.6%)
Prevalvuloplasty MR	
Grade 0	454
Grade 1	108
Pregnant patients	27
Children and adolescents (Age ? 20 years)	92
Extreme pulmonary hypertension patients	38 (7%)
Previous surgical commissurotomy	26

Values are represented as mean ± SD

Values in parentheses represent percentage of the total population

AF = atrial fibrillation; MR = mitral regurgitation

Successful results were defined as immediate post-procedure MVA ? 1.5 cm² and no MR grade > 2/4 according to Sellers' classification¹⁹. Eleven patients who originated from neighboring countries were lost to follow-up. The remaining 531 patients (98% of the 542 eligible) were followed for a mean of 8.6 ± 4.8 years (range: 1.5 to 18 years) and constitute the study population. Written informed consent was obtained from all patients prior to MBV.

Echocardiographic Examination

Two-dimensional (2-D) and Doppler echocardiographic studies were performed one to two weeks before the procedure, using commercially available equipment (Hewlett-Packard Unit Sonos 1500 and 5500). In addition to the mean transmitral valve gradient, the MVA was calculated from the Doppler study (using the pressure half-time method) and also by planimetry of the mitral valve orifice on the short-axis 2-D echocardiography view. Pulmonary artery systolic pressure was estimated by continuous-wave Doppler interrogation of the tricuspid regurgitant jet using the modified Bernoulli equation [$4 \times (\text{peak tricuspid regurgitant jet velocity})^2$] with 10 mmHg added for the estimated right atrial pressure. The morphological features of the mitral valve were semi-quantitated according to the mitral echocardiographic score (MES) as described by

Wilkins et al.²⁰. The mitral valve morphology was considered favorable if the MES was ? 8, and unfavorable if > 8. The echo-Doppler studies were repeated immediately after MBV, six months later, and annually thereafter for up to 18 years. Transesophageal echocardiography (TEE) was performed before MBV in patients with AF or history of systemic embolism, and in obese patients (body weight ? 80 kg) in whom the left atrium was not properly visualized by transthoracic echocardiography.

Mitral Balloon Valvuloplasty

All patients underwent MBV using the stepwise Inoue balloon technique as described previously^{6,7}. Standard hemodynamic measurements of right and left heart pressures were performed, in addition to simultaneous measurements of the left atrial and left ventricular pressures. The mean mitral gradient and MVA were calculated using the Gorlin formula, and cardiac output was determined with the Fick or thermodilution method. All hemodynamic measurements were obtained before and immediately after MBV. A computer (Micro-Siemens-Eléma AB, Solna, Sweden) was used to calculate the hemodynamic parameters. Left ventriculography was performed before and after MBV to assess the presence and severity of MR using the Sellers' classification¹⁹.

Follow-up

Clinical and echocardiographic assessments were carried out at six months after MBV and annually thereafter for up to 18 years. Event-free survival was assessed with events defined as death, mitral valve replacement (MVR) or redo MBV, and NYHA functional class III or IV. Restenosis was defined as a > 50% loss of the original increase in MVA, with follow-up MVA < 1.5 cm². Clinical evaluation was accomplished by direct interview of the patients at clinic visits. The follow-up was concluded in December 2007.

Statistical Analysis

Invasive and echocardiographic data obtained before and immediately after MBV, and also at long-term follow-up, were compared using Student's t-test (paired, two-tailed) for continuous data. Spearman's rank correlation (r) was used to measure the correlation between variables. Kaplan-Meier estimates were used to determine freedom from restenosis and event-free survival

(survival with freedom from redo MBV, MVR, cardiac death or NYHA class III or IV) for the whole group and also, separately, for patients with $MES \leq 8$ and $MES > 8$ and children compared to adults, patients with extreme pulmonary hypertension compared to the rest of the study group. Only patients with successful MBV were included in the analysis. The survival curves of all groups were compared using the log-rank test. A stepwise multivariable Cox regression analysis was used to identify predictors of restenosis and event-free survival. (The assumption of proportionality of hazard was assessed using Cox-Snell residuals; the log-negative-log of the survival function plot was a straight line ensuring validity of the proportionality assumption.) The variables included in the analysis were age, gender, baseline AF, echo score, pre-valvotomy NYHA functional class, pre- and post-procedural values for MVA, pulmonary artery pressure, and moderate MR. Descriptive statistics for the continuous variables are reported as median \pm 1 inter-quartile range. The type I error rate was set at $\alpha = 0.05$. Controlling the type I error at the nominal 0.05 level was achieved using Bonferroni's correction as a result of multiplicity. All data were entered prospectively in a computerized database, beginning in 1989. The analysis was performed with SAS Statistical Software (SAS v. 9.3; Statistical Analysis System SAS Institute, Inc., Cary, NC, USA).

Results

Pre-procedure clinical and morphological variables

Demographic characteristics of the patients are shown in Table 1. The mean age was 31 ± 11 (range: 10 - 61) years, the mitral echo score was 8.0 ± 1.1 , pre-valvuloplasty persistent AF was present in 71 patients (12.6%), 27 patients were pregnant, 26 patients had previous surgical commissurotomy, 92 patients were children or adolescents (range 10-20 years), and 38 (7%) patients had extreme pulmonary hypertension (pulmonary artery systolic pressure $> 75\%$ of systemic arterial pressure at rest).

Immediate hemodynamics results

The left atrial pressure, mean mitral gradient, and pulmonary artery systolic pressure decreased significantly after MBV with a corresponding increase in MVA from 0.84 ± 0.2 to 1.82 ± 0.53

Table 2: Baseline and Immediate Catheter Hemodynamic Results in 542 Patients Undergoing Successful Mitral Balloon Valvuloplasty (MBV)

Parameters	Value
Mean left atrial pressure (mmHg)	B: 26 ± 4.7
	I: $14.8 \pm 3.7^{***}$
Mitral mean mitral gradient (mmHg)	B: 14.4 ± 2.0
	I: $5.4 \pm 2.0^{***}$
Mitral valve area (cm ²)	B: 0.84 ± 0.2
	I: $1.82 \pm 0.53^{***}$
Cardiac Index (L/min/m ²)	B: 2.43 ± 0.47
	I: $2.94 \pm 0.76^{***}$
Pulmonary artery systolic pressure (mmHg)	B: 50 ± 18.5
	I: $40 \pm 13.8^{***}$
Post MBV MR	
Grade 0	372 (68.6%)
Grade 1	130 (24%)
Grade 2	40 (7.4%)

B = before valvuloplasty; I = immediately after valvuloplasty
MR= mitral regurgitation
Values are mean \pm SD.

***P < 0.0001 in comparison to baseline value

cm² ($p < 0.0001$) as measured at cardiac catheterization (Table 2), and from 0.92 ± 0.17 cm² to 1.95 ± 0.29 cm² ($p < 0.0001$) as measured by 2-D echocardiography (Table 3). A significant inverse relationship was found between MES and post-procedure MVA ($r = -0.33$; $p < 0.0001$). In comparison to patients with $MES > 8$, those with $MES \leq 8$ had a larger immediate MVA, whether measured by catheterization (1.92 ± 0.53 cm²; $p = 0.02$) or 2-D echocardiography (2 ± 0.3 cm²; $p = 0.009$). There was also a good correlation between post-procedure Doppler-derived MVA and 2-D echocardiographic MVA ($r = 0.55$, $p < 0.0001$). Mitral regurgitation was absent after the procedure in 372 patients, and recorded as grade 1 in 130 patients (24%) and grade 2 in 40 (7.3%).

Complications

There were no in-hospital deaths. Pericardial tamponade occurred in five patients, all of whom underwent pericardiocentesis, and MBV was carried out successfully a few months later. Cerebral thromboembolic events occurred in three patients (0.5%), all of whom were in AF and receiving warfarin before the procedure. TEE was not routinely carried out before MBV during the early stages of the study. One of these three patients recovered completely, and two developed

Table 3: Baseline, Post-Procedural and Final Follow-up Clinical and Echocardiographic Data in 531 Patients Undergoing Successful Mitral Balloon Valvuloplasty (MBV)

Parameters	Values
Doppler mean mitral gradient (mmHg)	B: 13.5 ± 2.6 I: 5.2 ± 1.4*** F: 6.2 ± 3.0***
Doppler MVA (cm ²)	B: 0.91 ± 0.17 I: 1.97 ± 0.28*** F: 1.55 ± 0.42***
2-D echo MVA (cm ²)	B: 0.92 ± 0.17 I: 1.95 ± 0.29*** F: 1.6 ± 0.4***
Pulmonary artery systolic pressure (mmHg)	B: 48.6 ± 17.3 F: 32.0 ± 10.7***
Restenosis	165/531 (31%)
Atrial fibrillation at follow-up	96/531 (18%)

B = before valvuloplasty; I = immediately after valvuloplasty; F = follow-up
 MVA = Mitral valve area
 ***P < 0.0001 (immediate results compared to pre-MBV, follow-up results were compared to immediate results)

stroke. A small atrial septal defect (ASD) was detected by Doppler colour flow mapping immediately after MBV in 131 patients (23%). The ASD had closed spontaneously in almost all patients at six to 12 months after MBV, and in none

Table 4: Procedure-related complications in 562 patients undergoing MBV

Variable	n(%)
Procedural death	0
Cardiac tamponade	5 (0.8%)
Cerebral embolism	3 (0.53%)
Stroke	2 (0.36%)
Post-procedure ASD	131/562 (23.3%)
MR post MBV ? 3	9 (1.6%)

MR = Mitral regurgitation; MBV = Mitral balloon valvuloplasty
 ASD = Atrial septal defect.

of the patients did it require closure by either catheter intervention or surgery. Severe MR was encountered in nine patients (1.6%) (Table 4).

Clinical and Echocardiographic follow-up

Eleven patients (all originating from neighboring countries) were lost to follow-up; all had similar demographic characteristics to the remainder of the study population (mean age 32 ± 10 years, MES 7.8 ± 1, immediate MVA 1.92 ± 0.26 cm²). The remaining 531 patients (98% of those eligible) were followed up at clinic visits with clinical and echocardiographic examination for a period of 8.3 ± 4.8 years (range: 1.5 to 18 years). The MVA at the final follow-up (1.6 ± 0.4 cm²) and was larger in patients with favorable mitral valve morphology (MES ? 8) (1.8 ± 0.37 cm²) (P = 0.004). New onset AF was encountered in 40

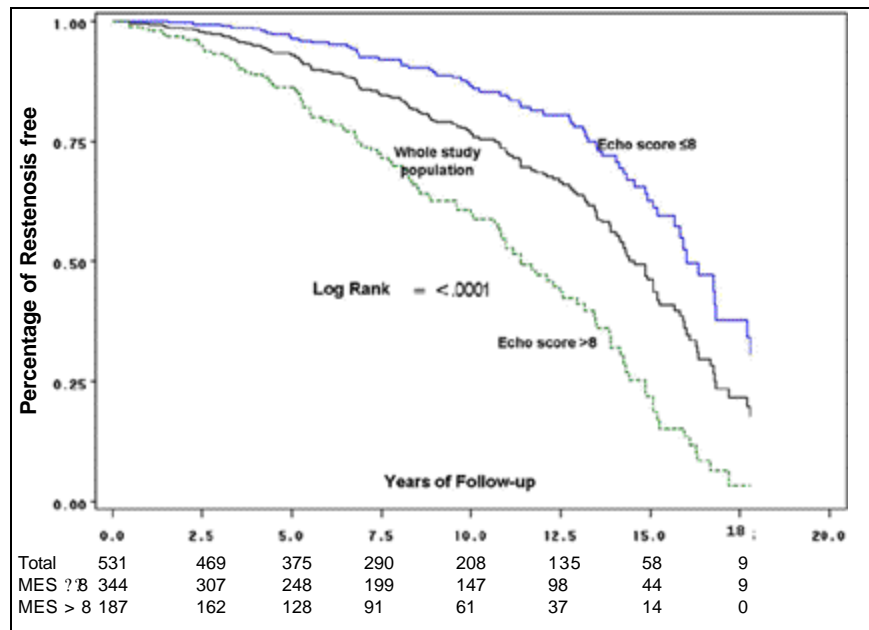


Fig.1: Freedom from restenosis by Kaplan-Meier estimates for all patients and for patients with MES ? 8 and > 8. Numbers shown below the graph represent patients alive and uncensored at each year of follow-up.

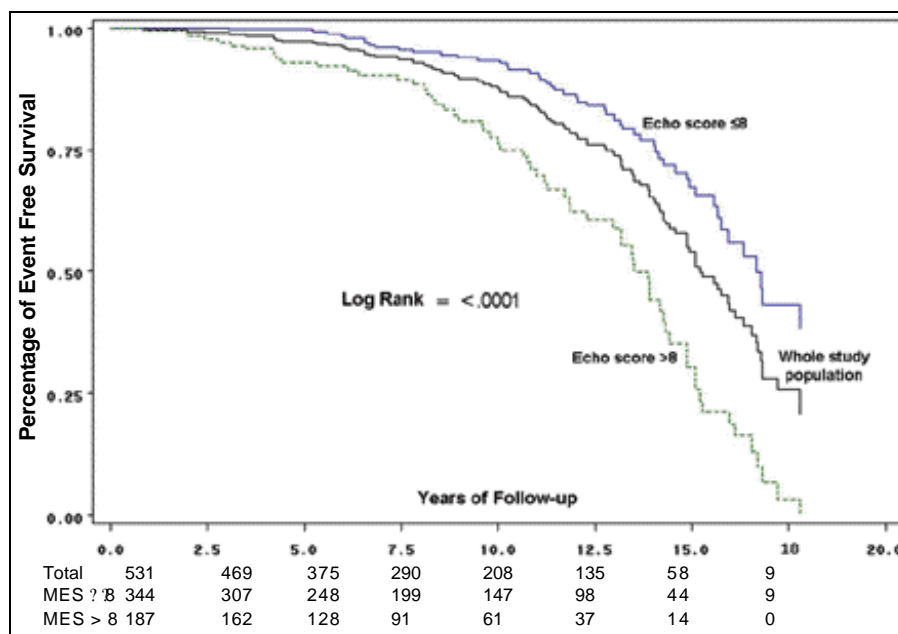


Fig.2: Kaplan-Meier event free survival estimates (alive and free from redo MBV, MVR, NYHA class III or IV) for all patients and for patients with MES ≤ 8 and > 8. Numbers shown below the graph represent patients alive and uncensored at each year of follow-up.

patients (7.7%) at follow-up, and the prevalence of AF at follow-up was 96 of 531 (18%) (Table 3).

Restenosis

Restenosis was encountered in 165 of 531 patients (31%) who had successful MBV, and occurred less frequently in those with MES ≤ 8 (19%). Stepwise multivariable Cox regression analysis identified MES > 8 ($p < 0.0001$) and previous mitral surgical commissurotomy ($p = 0.043$) as predictors of restenosis. Values for actuarial freedom from restenosis at 10, 15, and 18 years were $77 \pm 2\%$, $46 \pm 4\%$ and $18 \pm 4\%$, respectively. These values were significantly higher for patients with MES ≤ 8 ($86 \pm 2\%$, $62 \pm 4\%$, $31 \pm 7\%$, respectively; $p < 0.0001$) (Fig. 1).

Follow-up events

Cumulative events included 13 deaths, 51 redo MBV and 50 MVR accounting for a total of 114 patients with combined events. The remaining 417 patients were free of combined events (death, MVR, redo, MBV, NYHA class III or IV). The event-free survival rates at 10, 15 and 18 years were $88 \pm 1\%$, $53 \pm 4\%$ and $21 \pm 5\%$, respectively, and were significantly higher for patients with MES ≤ 8 ($93 \pm 2\%$, $65 \pm 5\%$, $38 \pm 8\%$, respectively) ($P < 0.0001$) (Fig 2). The predictors of combined events were MES > 8 ($P < 0.0001$) and baseline AF ($P = 0.03$).

Mitral balloon valvuloplasty in patients with persistent atrial fibrillation at baseline

Seventy-one patients with persistent baseline AF underwent MBV (12.6%). In comparison to patients in sinus rhythm, these subjects were older (mean age 42 ± 12 vs. 30 ± 10 years) and had higher MES (8.45 ± 1.14 vs. 7.9 ± 1 ; $P = 0.005$) than those in sinus rhythm. In patients with AF, MBV resulted in inferior immediate and long-term results as reflected in smaller immediate MVA 1.89 ± 0.23 cm² vs. 2.0 ± 0.39 cm² ($P = 0.005$), smaller follow-up MVA 1.49 ± 0.39 cm² vs. 1.6 ± 0.4 cm² ($P = 0.037$) and higher restenosis rate (44% vs. 31%; $P = 0.012$). Patients in AF had lower event-free survival at 10 years (72%) than those in sinus rhythm (89%) ($P = 0.029$).

MBV during pregnancy

The study included 27 pregnant patients (mean age 31 ± 8 years) with baseline clinical and echocardiographic characteristics similar to the remainder of the study population. During their second or third trimesters, these patients were severely symptomatic (NYHA class III or IV), and seven of them developed pulmonary edema in spite of maximal medical treatment. In these 27 patients, the MVA was increased from $0.88 \pm$

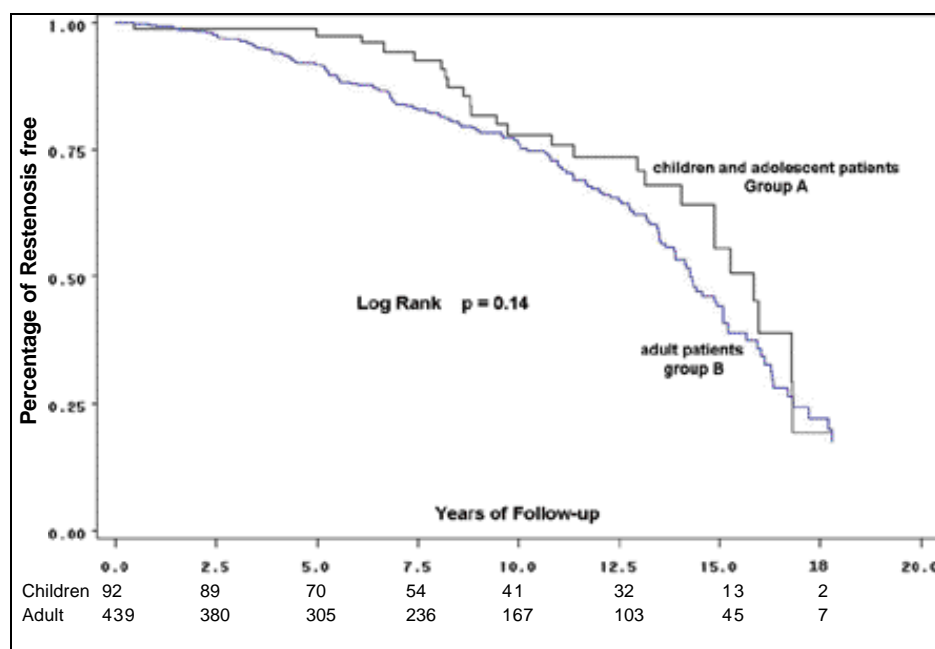


Fig.3: Freedom from restenosis by Kaplan-Meier estimates for group A (children and adolescents) and group B (adult) patients. Numbers shown below the graph indicate patients alive and uncensored at each year of follow-up.

0.17 cm² before MBV to 1.97 ± 0.35 cm² immediately after MBV and at follow-up it was 1.7 ± 0.43 cm². There were no maternal or fetal deaths, and all patients delivered at full term by vaginal delivery.

Mitral valvuloplasty in children and adolescents

Ninety-two (17.3%) out of 531 patients who underwent successful MBV were children and adolescent with mean age 17 ± 2.78 years (range 10-20 years). In comparison to the adult patients these subjects had lower echo score (7.6 ± 1.26 vs. 8.1 ± 1; *P* = 0.0005), smaller Doppler baseline MVA (0.84 ± 0.17 cm² vs. 0.92 ± 0.16 cm²; *P* < 0.01), and larger post procedure MVA (2.0 ± 0.3 cm² vs. 1.96 ± 0.27 cm²; *P* < 0.01). There was no significant difference in the incidence of restenosis between this group and the adult patients group (27% vs. 31%, respectively; *P* = 0.37). Multivariable analysis identified MES > 8 as predictor of restenosis. Actuarial freedom from restenosis for children at 10, 15, 18 years were 80 ± 5%, 56 ± 8%, 19 ± 10% vs. 77 ± 2%, 44 ± 4%, 17 ± 4% for adults, respectively (*P* = 0.14) (Fig 3). Event-free survival rate at 10, 15, 18 years for children were 85 ± 4%, 55% ± 9%, 17 ± 1% vs. 88 ± 1%, 54 ± 4%, 21 ± 6% for adults, respectively (*P* = 0.77) (Fig 4).

Mitral valvuloplasty in patients with extreme pulmonary hypertension

Thirty-eight (7%) out of 531 patients undergoing successful MBV had extreme pulmonary hypertension, defined as pulmonary arterial systolic pressure > 75% of systemic systolic arterial pressure at rest (range 80-130 mmHg). In comparison to the remaining 493 patients, these subjects were of similar age (30.7 ± 8.8 vs. 31 ± 11 years; *P* = 0.66), had higher MES (8.45 ± 0.9 vs. 8 ± 1.1; *p* = 0.004), higher pulmonary vascular resistance (857 ± 384 dyne/sec/cm⁻⁵ vs. 227 ± 197 dyne/sec/cm⁻⁵; *p* < 0.0001), equal left atrial mean pressure (27.3 ± 5.3 mmHg vs. 25.9 ± 4.7 mmHg; *p* = 0.08), smaller baseline and post-procedure MVA (0.7 ± 0.16 cm² vs. 0.85 ± 0.19 cm² (*p* < 0.0001) and 1.66 ± 0.43 cm² vs. 1.83 ± 0.53 cm², respectively; *P* = 0.027), similar restenosis rate at follow-up (12/38 (31%) vs. 153/493 (31%); *p* = 0.94). The combined events in those patients were one death, three redo MBV, three patients underwent MVR, a total of 7 patients. The remaining 31 patients were in NYHA class I or II and the event-free survival rate at 10 and 15 years (76 ± 1%, 45 ± 1% vs. 88 ± 1%, 55 ± 4%, respectively; (*p* = 0.039) (Fig 5). Pulmonary hypertension was normalized within 12 months. However, the pulmonary artery pressure was raised in the last follow-up in 12 patients who developed restenosis to (54 ± 24 mmHg vs. 31 ± 55 mmHg) for the remaining 26 patients.

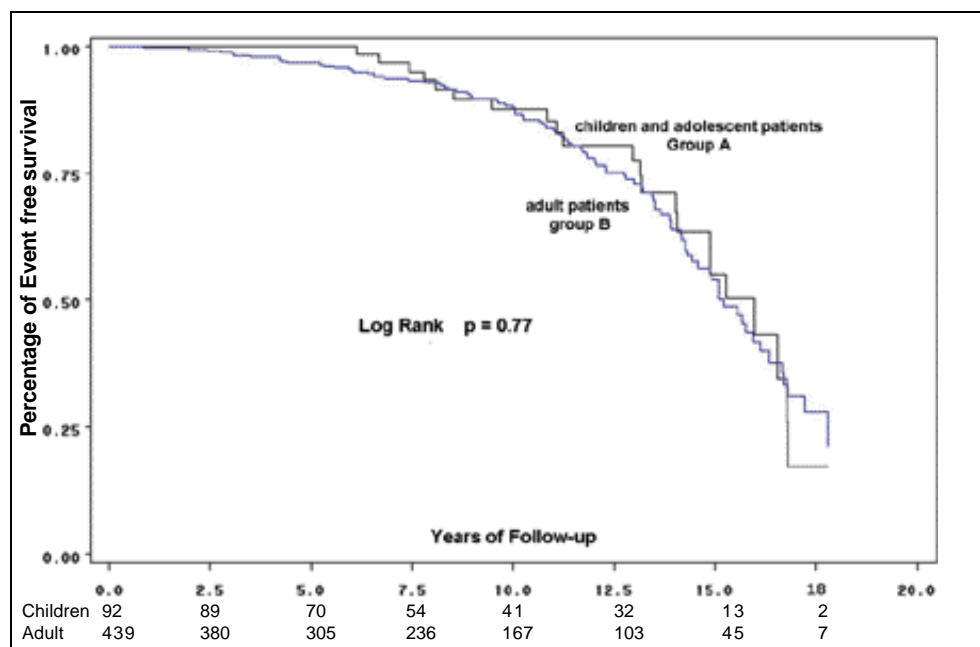


Fig.4: Kaplan-Meier event free survival estimates (alive and free from redo MBV, MVR, NYHA Class III or IV) for (children and adolescent) patients and adult patients. Numbers shown below the graph indicate numbers of patients alive and uncensored at each year of follow-up.

Discussion

Although, previously, several groups have described the salutary immediate and mid-term results of MBV for the treatment of severe MS¹⁻¹³, long-term echocardiographic follow-up studies of MBV are few¹⁴⁻¹⁸. To our knowledge, the present study relates to one of the longest periods of follow-up among a large series of patients following MBV.

Immediate results

There was a significant inverse relationship between mitral valve morphology, as characterized by the MES, and immediate post-procedural MVA. Therefore, mitral valve morphology was the best predictor of post-procedural mitral opening, a finding which concurred with reports from other investigators^{13-17,20}. However, good results can still be obtained in patients with relatively high MES. Although some increase in MR immediately post-valvuloplasty was frequent, severe MR was rather uncommon in the present series and occurred mainly in patients with high MES.

Complications

The Inoue balloon catheter is characterized by its low complication rate in comparison to the

reported results of the double-balloon technique⁷. Cerebral embolism was encountered in three patients (0.5%) in the present study (all in AF), which was significantly less compared to that in previous reports, where the proportion ranged between 1 and 2%^{2,4}. It is recommended that TEE be performed in all patients in AF or those with prior history of thromboembolism, or when the left atrium is not properly visualized by transthoracic echocardiography (TTE) because of obesity or emphysematous chest, and also when the mitral valve morphology is not adequately assessed by TTE. It is not recommended that TEE be performed routinely before MBV.

Restenosis

The overall restenosis rate among the present patients was 31%, and was lower in patients with echo score ≥ 8 (19%). The restenosis rate after MBV has been reported to range from 3% to 70% at one to three years⁹⁻¹¹. The restenosis-free probability of 77% at 10 years, 46% at 15 years and 18% at 18 years concurred with that reported by Ben Farhat et al.¹⁶ (66% at 10 years) in a similar patient population (mean age 33 ± 13 years). In contrast, Hernandez et al.¹⁵ reported a 39% restenosis rate at seven years in an older patient population (mean age 53 years). The restenosis-free probability was higher in patients

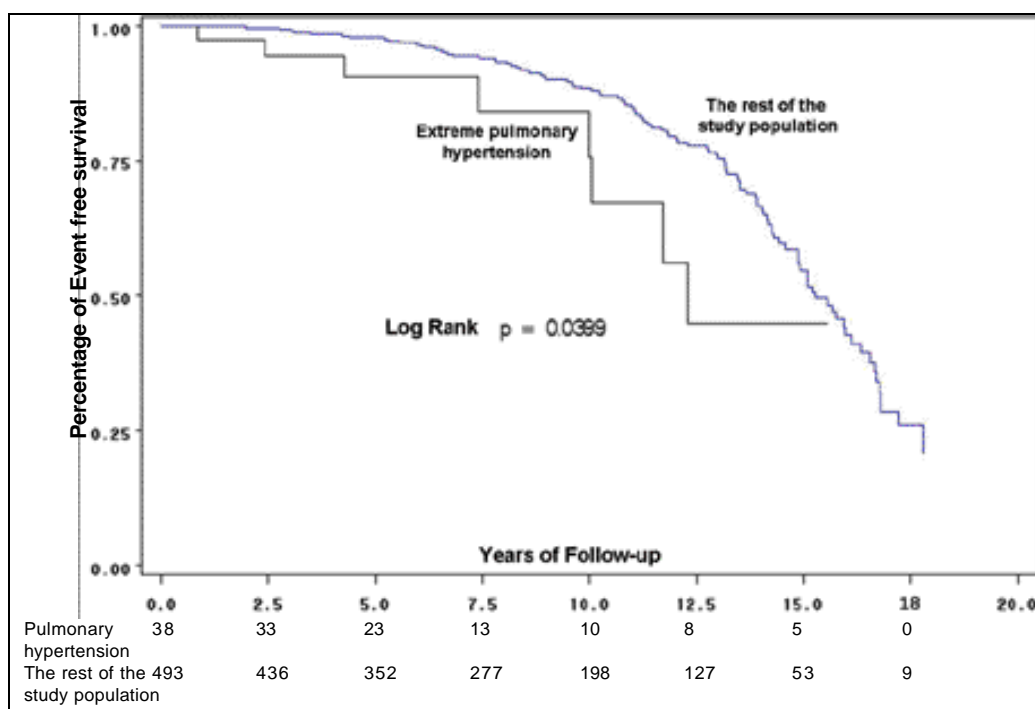


Fig.4: Kaplan-Meier event free survival estimates (alive and free from redo MBV, MVR, NYHA Class III or IV) for patients with extreme pulmonary hypertension and the rest of the study population. Numbers shown below the graph represent patients alive and uncensored at each year of follow-up.

with MES ≤ 8 (86% at 10 years, 62% at 15 years and 31% at 18 years). In our series, the predictors of restenosis were high MES > 8 and previous mitral commissurotomy. These findings concurred with the reports of other investigators^{9,13-17}.

Event-free survival

The event-free survival rates at 10, 15 and 18 years for patients with successful MBV were 88%, 53% and 21%, respectively and were significantly higher for patients with MES ≤ 8 (93%, 65% and 38%, respectively). These findings concurred with those reported by Ben Farhat et al.¹⁶, and compared favorably with the long-term, event-free survival data reported by others. For example, Cohen et al.¹³ found a 51% event-free survival at six years in 146 patients following MBV (mean age 59 years, MES 7.7). Similarly, lung et al.¹⁴ reported a 10-year event-free survival rate of 61% in 528 patients with successful MBV (mean age 49 years). Hernandez et al.¹⁵, reporting on 561 patients with a successful procedure and mean age of 53 years, found a seven-year event-free survival rate of 69% for the whole group, and 88% for a subgroup with low MES. Palacios et al.¹⁷, reporting on 879 patients with a

successful procedure and a mean age of 55 years, identified 12-year event-free survival rates of 38% and 22% for patients with MES ≤ 8 and > 8 , respectively. Differences in age, clinical characteristics and valve morphology may account for the worse long-term, event-free survival in the above reports from the United States and Europe compared with that of the present series. Accordingly, the long-term results of the present study population cannot be extrapolated to the older patient populations reported elsewhere. Furthermore, the results of the present study highlighted the impact of mitral morphology on the long-term outcome.

Mitral valvuloplasty during pregnancy

Mitral balloon valvuloplasty using the Inoue technique for severe MS during pregnancy was shown to be safe, and to provide satisfactory clinical and hemodynamic results and long-term outcome compared to those observed in larger patient populations without pregnancy²¹. If possible, MBV should be avoided during the first trimester, and also performed by experienced operators with adequate abdominal and pelvic shielding to ensure minimum exposure to radiation.

Mitral valvuloplasty in patients with persistent baseline atrial fibrillation

Atrial fibrillation occurs more frequently in older patients and is associated with inferior immediate and long-term results after MBV, a finding that concurs with the reports of other investigators²²⁻²⁵. However, the presence of AF by itself does not unfavourably influence the outcome but it is a marker for clinical and morphological features associated with inferior results after MBV. Thus, patients in AF with MES \leq 8 had equal post-procedure and follow-up MVA compared to patients in sinus rhythm. These findings concur with reports of other investigators^{22,23}.

Mitral valvuloplasty in children and adolescents

Mitral balloon valvuloplasty is safe and effective in children and adolescents with rheumatic MS. The immediate results of this procedure are slightly better in this young age group than in adults, with excellent long term results that are comparable to those seen in adults^{26,27}. It has been hypothesized that children and adolescent patients may be more prone to developing restenosis because of the increased likelihood of smoldering rheumatic activity or recurrence of rheumatic fever in this age group. This hypothesis is not supported in our series where the restenosis rate was similar to that in the adult patients. Although no link was established between restenosis and recurrence of rheumatic fever in our population, the absence of instances of recurrence of rheumatic fever confirms the effectiveness of long-term prophylactic antibiotic treatment. Unfavourable mitral valve morphology (MES $>$ 8) is the important predictor of worse long-term outcome for both children and adults^{26,27}.

Mitral valvuloplasty in patients with extreme pulmonary hypertension

Thirty-eight (7%) out of 531 patients undergoing successful MBV had extreme pulmonary hypertension, an incidence similar to the 8.2% reported by Ward et al²⁸. Extreme pulmonary hypertension carries a very poor prognosis with a mean survival of less than 3 years²⁸. The severity of pulmonary arterial hypertension is often out of proportion to the degree of left atrial hypertension, reflecting a major increase in

pulmonary vascular resistance 857 ± 384 dyne/sec/cm⁻⁵ vs. 277 ± 197 dyne/sec/cm⁻⁵ for the rest of study population in spite of equal left atrial pressure at baseline²⁹⁻³¹. Surgical commissurotomy for patients with MS with extreme pulmonary hypertension carries high risk (11%-13%) of operative mortality^{28,32}, in contrast to the 0% mortality seen in our patients submitted to MBV. This study also demonstrated normalization of pulmonary artery pressure within 12 months after successful MBV²⁹⁻³¹. However, the pulmonary artery pressure increase again in the 12 patients who developed restenosis albeit not to the same level compared to the pre MBV level. We also observed worse event free survival rate in the pulmonary hypertensive group compared to the rest of the study population, it could be explained due to the fact that pulmonary hypertensive patients had higher echo score.

Comparison of mitral valvuloplasty with surgical commissurotomy

MBV is associated with less morbidity, shorter hospital stay, and avoidance of the discomfort and other problems associated with thoracotomy, while the cost of surgery is at least twice that of MBV in the United States³³. The immediate results appear to be very similar to closed and open surgical commissurotomy³³⁻³⁷, while operative mortality from closed commissurotomy (2.97%) was higher than that reported after MBV (0-0.5%)^{4,18}. The only long-term, though relatively small (30 patients in each group), randomized study comparing surgical closed, open, or percutaneous commissurotomy, has been reported by Ben Farhat et al.³⁷ in young population with pliable, non-calcified mitral valves. The 7-years results were better for open and percutaneous procedures than for closed commissurotomy as assessed by a higher event-free survival (93, 90, and 50%, respectively), better follow-up MVA (1.8, 1.8, and 1.3 cm²) and lower restenosis rate (6%, 6%, and 37%). In a long-term surgical series involving 103 patients (mean age 38 years) submitted to closed mitral commissurotomy, Hickey et al³⁹ reported event-free rate from MVR of 78% at 10 years and 47% at 20 years. Rihal et al⁴⁰ reported on 267 patients (mean age 43 years) event-free rate from MVR 57% at 10 years and 24% at 20 years. In our series, the combined event-free rates after MBV (88% at 10 years, 53% at 15 years and 21% at 18 years) were not worse than those of surgical series.

Study limitations

One limitation of the present study was that 11 patients were lost to follow-up. However, as their demographic characteristics and immediate post-procedural findings were similar to those of the main study population, such loss should not have affected the study findings.

Conclusion

MBV provides excellent long-term results for up to 18 years in patients with favorable mitral valve morphology, although patients with a less favorable anatomy may still obtain reasonably acceptable hemodynamic and symptomatic relief. MBV is safe and effective in children with excellent long-term results that are comparable to those seen in adults. MBV is also safe and effective in patients with extreme pulmonary hypertension. More importantly, the long-term outcome following MBV can be predicted from baseline clinical and valvular characteristics. ?

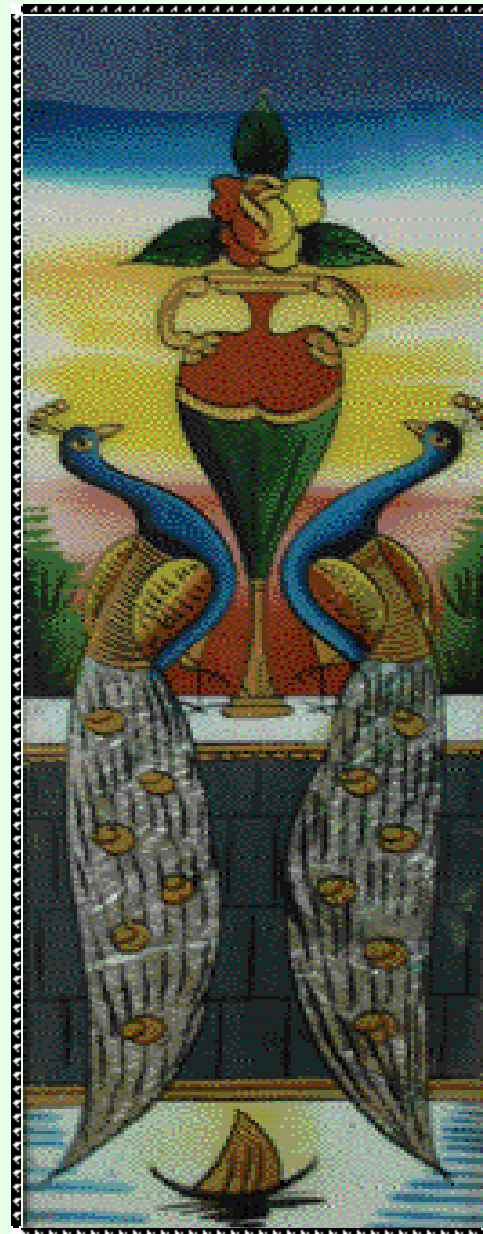
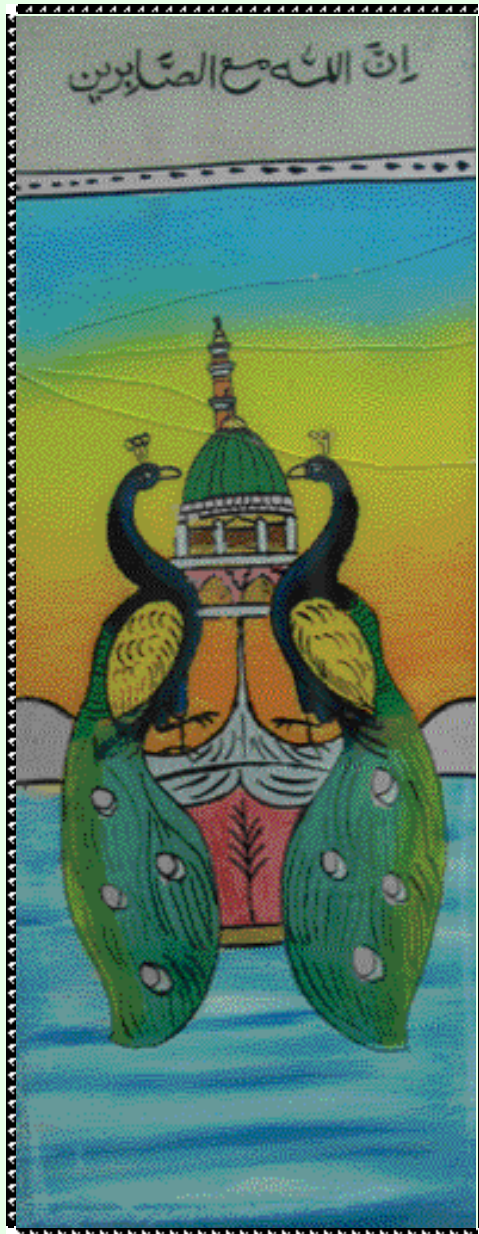
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Stained glass wall decoration common in Arabian Gulf.