Aim: To study the immediate and long-term results of percutaneous balloon mitral valvuloplasty (PBMY) in patients with severe mitral stenosis and to determine the predictors of restenosis.

Patients and Method: Consecutive patients presented to King Khalid University Hospital, Riyadh, Saudi Arabia during the period from 1999 to 2003. Two hundred fifteen patients with severe symptomatic mitral stenosis submitted to PBMY using the Inoue technique. The morphological features of the mitral valve were graded using Wilkin's echocardiography score. Clinical and echocardiography data were available on follow-up on 195 patients (90.6%), 46 male and 149 females. Mean age was 32 ± 10.9 years with a mean follow-up 96 ± 28 months (11 month to 11 year).

Result: The procedure was successful (i.e. MVA ≥ 1.5 cm² and mitral regurgitation (MR) < 3) in 205 patients (95%), without mortality. MVA increased from 0.98 ± 0.27 cm² to 2.02 ± 0.29 cm² (P<0.0001). Acute complication occurred in 5 patients, 3 had cardiac tamponade (1.4%) and 2 had severe MR (0.9%). There were no cases of cerebral embolism. Fifteen patients (7%) had mild worsening of MR and 19 patients (8%) has insignificant interatrial shunt. The restenosis rate on follow-up was 16.4%. The predictors of restenosis were the echo score and immediate mitral valve area.

Conclusion: Our data showed that PBMY is a safe procedure with good immediate and long-term outcome. The restenosis predictors were the morphological features of the mitral valve and the area achieved at dilatation.

Introduction

ALTHOUGH THE TECHNIQUE of surgical commissurotomy was first described as early as 1948, percutaneous balloon mitral valvuloplasty (PBMV) became a feasible option with the advent of the Inoue balloon 1984. Two years later Zaibag MA et al described the double balloon technique. PBMV is now the treatment of choice for many patients with symptomatic mitral stenosis.

Numerous large series have reported excellent short, medium and long-term outcomes with a low incidence of serious complications. A randomized trial comparing PBMV with the surgical alternatives of open or closed commissurotomy demonstrated equivalent outcomes. An echocardiographic scoring system developed by Wilkin's and colleagues was found to be particularly valuable in patient selection and has been widely adopted. Cannon et al showed that the magnitude of pre-procedural commissure calcification bore a strong relation to procedural success irrespective of the overall score.

Our study represents a single center experience with a single operator using the Wilkin's score to select our patients for PBMV with adequate long-term follow-up to predict the outcome and assess the factors that predispose to restenosis.

Patients and Methods

During the period from January 1992 to January 2003, 215 consecutive patients were...
subjected to PBMV at King Khalid University Hospital. All patients with symptomatic severe mitral stenosis were considered. Patients were excluded if their echocardiographic score ≥ 11, if there were significant mitral regurgitation ≥ 3, the presence of left atrial thrombus, recent embolic events, atrial septal aneurysm and significant other valvular heart disease. Transthoracic and transesophageal echocardiography were performed before the procedure for all patients.

**Technique of PBMV:**

The procedure was performed in the fasting state under mild sedation and covered by a beta-blocker. Patients underwent diagnostic right and left cardiac catheterization with hemodynamic measurement and cardiac output assessment by thermodilution technique. The mitral valve area was calculated. Cine left ventriculography was performed before and after PBMV. All procedures were done by the Inoue technique. Following transeptal puncture, systemic anticoagulation was achieved by intravenous administration of 150 unit/kg body weight of heparin. A stainless steel guide wire was advanced through the transeptal catheter and placed with its tip coiled in the left atrium and the transeptal catheter was removed. A 14 French dilator was advanced over the guide wire and used to dilate the femoral vein and the atrial septum. A balloon catheter chosen according to the patient's height was advanced over the guide wire into the left atrium. The distal part of the balloon was inflated and advanced into the left ventricle with the help of the spring wire stylet, which had been inserted through the inner lumen of the catheter once the catheter was in the left ventricle. The partially inflated balloon was moved back and forth inside the left ventricle to assure that it was free of the chordae tendineae. The catheter was then gently pulled against the mitral plane until resistance was felt. The balloon was then rapidly inflated to its full capacity and deflated quickly. The catheter was withdrawn into the left atrium and the mitral gradient and cardiac output were measured. If further dilatation were required, the stylet was introduced again and the sequence of steps described above repeated at a larger balloon volume. After each dilatation, its effect was assessed by pressure measurement and at times echocardiography. If mitral regurgitation occurred further dilatation of the valve was stopped.

Protamine sulphate was administered intravenously to reverse the effect of heparin. Patients were discharged on the 2nd day of the procedure after repeating transthoracic echocardiography. Patients were followed at the cardiology clinic at 3 and 6 months and then yearly. Transthoracic echocardiography was done at each visit to assess for sign for restenosis.

**Statistical Analysis:**

Data were analyzed by the paired students t test using the Microsoft Excel statistical package and presented as means ± standard deviation. The level of statistical significance was set at P<0.05.

**Results**

PBMV was attempted on 215 patients. Early on there were 5 cases of technical failure due to either failure to cross the interatrial septum or the mitral valve. The success rate, defined as MVA ≥ 1.5 cm² and MR < 3, was 95% for the whole group. However, the failure rate was reduced from 5% to 0.9% in the last 100 patients. Table 1 shows the patient clinical characteristics. The majority were females; non-Saudis were almost half of the patients, which represents a unique population. Most of the patients were in class III (NYHA)
cases. Table 2 shows the hemodynamic assessment pre-and-post dilatation. The mitral valve area increased from 0.86 ± 0.26 to 1.90 ± 27 (P<0.001) by invasive assessment with dropping in mean gradient across the mitral valve from 19.4 ± 6.8 to 5.6 ± 2.1 (P<0.0001). Pulmonary artery pressure also dropped from 65 ± 17.6 to 47.2 ± 15.6 (P>0.001).

Table 3 shows acute complications. There was no mortality. Three patients developed acute cardiac tamponade at the time of interatrial septal puncture. All were managed successfully without mortality. Severe mitral regurgitation developed in 2 patients and required mitral valve replacement during the same admission. Both valves had a high echo score > 8. Mild worsening of mitral regurgitation developed in 15 patients (7%) and interatrial communication developed in 19 patients (8.8%). On follow-up of the shunt, the size reduced gradually and none were hemodynamically significant.

Follow-up:

Table 4 shows the long-term follow-up. One hundred ninety-five patients completed follow-up (90.6%) for 11 months to 11 years. There were 32 patients (16.4%) who had restenosis (i.e. MVA < 1.5 cm²). The predictor of restenosis was high echo score. Twenty-three patients (11.8%) had a mitral valve area < 1.8 cm² in 11 patients (5.6%). There was no mortality on the follow-up group. Fifteen patients underwent repeated dilatation while the other 17 patients went for mitral valve replacement due to high echo score.

Discussion

As experience with PBMV has grown, the incidence of complication has declined and the success rate has increased. B. Lung et al (18) analyzed their experience from 1986 to 2000 on 2538 consecutive patients. Technical failure decreased from 6.0% in 1986-87 to 4% in 1988 and 0.7% for the following years. The incidence of tamponade decreased from 1.4% in 1986-87 to 0.1% for the following years. Reviewing our last 100 patients, the failure rate has decreased from 5% to 0.9% and there was no tamponade or severe mitral regurgitation.

Data from large series indicate that the prediction of the outcome following PBMV is multifactorial and based not only on morphological characteristics of the valves but also a number of clinical and procedural variables including age, functional class, effective balloon dilating area and the final valve area, (18,19,20).

Palacios et al analyzed 879 patients and followed them for a mean of 4.2 ± 3.7 years. Cox regression analysis identified post PBMV mitral regurgitation ≥ 3+, echo score > 8, age, previous surgical commissurotomy, NYHA class IV, pre PBMV mitral regurgitation ≥ 2+ and higher post PBMV pulmonary pressure area as independent predictors of combined events at long-term follow-up (21).

M.E. Fawzy et al analyzed the long-term results of 362 patients and grouped them according to the
echo score. Logistic regression analysis identified echo score and post procedure MVA <2.0 as strong predictors of restenosis. The restenosis rate was 12% in the group with an echo score < 8 and 25% in the group with an echo score > 8 (P<0.001). Restenosis in all patients was 15%27.

The average restenosis rate has been less than 20%23. In our studies, the data were consistent with this estimate. We found a restenosis rate of 16.4%. The importance of commissural assessment in predicting the outcome following the procedure have been emphasized in several studies24-29. In a Parisian series of 422 patient with calcific mitral stenosis (assessed by means of a fluoroscopic score) a good immediate results following PBMV was obtained in 76%. However, late deterioration was frequent during follow-up, particularly following an initial suboptimal result. Multivariate analysis demonstrated the importance of a number of clinical and echocardiographic variables on initial and long-term outcome, including the extent of calcification27.

More recently, Weit et al confirmed that commissural calcification has an adverse effect on the clinical results of PBMV25. With regard to age, Kinsara AJ et al compared a young age group (mean age, 17 ± 3 years) and older group (mean age, 35 ± 10 years). The outcome was comparable and the benefit was similar in each group on completion of follow-up29. We have a similar mean age to the adult group of Kinsara et al study and the outcome was similar.

We excluded from our study all those who had an atrial thrombus. However, a recent trial by Silaruks S et al followed patients with left atrial thrombus for 6 months on anticoagulation and found complete resolution of the thrombus by 6 months in 24.2% of the cases, which makes them candidates for PBMV30.

Systemic anticoagulation was used as the standard practice in our study. Bozat T, et al reported their experience in 134 patients without anticoagulation and they concluded that avoidance of heparin did not lead to an increase in emboli complication. The vascular access was withdrawn early, thereby reducing the duration of hospital stay and time of ambulation7.

In developing countries, the application of PBMV is frequently limited on account of the high cost of the Inoue balloon. The development of the percutaneous metallic valvulotome, which can be autoclaved after each procedure to allow repeated use in many patients, may help to overcome these problems. Initial data have been encouraging2,23.

Conclusion

The short-term advantages and excellent long-term results of PBMV indicate that it is now the procedure of choice in patients with mitral stenosis in whom the valve area anatomically suitable. Use of the Inoue balloon is now widespread and this will remain the technique of choice for the foreseeable future.

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References