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Original Article

Safety and efficacy of percutaneous balloon mitral valvotomy in severe mitral stenosis with moderate mitral regurgitation – A prospective study

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ABSTRACT

Background: Percutaneous balloon mitral valvotomy (PBMV) is generally considered as a contraindication in patients with mitral stenosis (MS) associated with moderate to severe mitral regurgitation (MR). We sought to compare the safety and efficacy of PBMV in patients with severe MS and with moderate MR with those with less than moderate or no MR.

Materials and methods: Symptomatic patients of MS with mitral valve area $\leq$1.5 cm^2 were screened into two groups: Group I with moderate MR and Group II with less than moderate or no MR. Clinical and echocardiographic assessments were done at 24 h, 1 month, and 6 months post-procedure. A treadmill testing was done prior to PBMV and at 6 months.

Primary safety outcome was a composite of cardiovascular death and development of severe MR with or without requirement for mitral valve replacement at 30 days of procedure. Efficacy of the procedure was measured as improvement in functional class, treadmill time, and mitral valve area (MVA) at 6 months.

Results: Seventeen patients with moderate MR and 208 patients with less than moderate MR underwent PBMV. Primary outcome showed no significant difference [2 (11.7%) in Group I *vs.* 8 (3.85%) in Group II, $p = 0.36$]; occurrence of severe MR was higher in Group I [RR = 4.87, 95% C.I. = 1.42–16.69]. In Group I patients, improvement in treadmill time was seen in 12 (70.59%), functional class in 13 (76.47%), and MVA in all patients.

Conclusion: In patients having severe MS associated with moderate MR, PBMV may be a safe option and provides sustained symptomatic benefit.

1. Introduction

Rheumatic heart disease (RHD) remains a major public health problem in India. A survey of secondary care hospitals shows that nearly 30% of cardiac cases are related to RHD.[1] As per WHO estimates, nearly 0.133 million deaths annually were attributable to RHD in the Southeast Asia region.[2] Severe mitral stenosis (MS) is the major cause for hospital admissions and limitations in the functional capacity of patients with RHD. Percutaneous balloon mitral valvotomy (PBMV) is a safe and effective treatment for symptomatic severe MS [mitral valve area (MVA) <1.5 cm^2] with favorable valve morphology. Presence of moderate mitral regurgitation (MR) is considered a contraindication to PBMV.[3] It is estimated that around 40% of all patients with RHD have combined MS and MR.[4] A significant proportion of patients with symptomatic severe MS have associated moderate MR. These patients are referred for mitral valve replacement (MVR), even though they otherwise have no indication for MVR, exposing them to surgical risk and long-term risks of anticoagulation and infective endocarditis. Preserving the native valve with relief of obstruction is an attractive option for this subset of patients.

2. Aims and objectives

We hypothesized that symptomatic patients with severe MS and associated moderate MR can be safely subjected to PBMV

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without increased mortality or need for urgent MVR and can have significant symptom alleviation.

The primary aim was to examine whether the composite of cardiovascular death and severe MR with or without requirement of MVR in patients undergoing PBMV for severe MS was significantly different in those having associated moderate MR as compared to those with mild or no MR. The secondary aim was to see whether patients undergoing PBMV for MS and associated moderate MR had improvement in their functional status and MVA after the procedure and had sustained symptomatic benefit at 6 months.

3. Patients and methods

Our study was a prospective cohort study approved by the Institutional Ethics Committee. Consecutive patients with symptomatic severe MS [2D-MVA $< 1.5\ cm^2$] were screened. These patients were evaluated clinically by transthoracic echocardiography [TTE] and transesophageal echocardiography [TEE] for the presence and severity of associated MR and suitability for PBMV. Patients with severe MR, valves with unsuitable morphology (patients with Wilkins score >12 and those with heavy mitral valve calcification as judged by echocardiography and/or fluoroscopy), left atrial clot, requiring cardiac surgery for other indications, and those who refused to give consent were excluded. We divided patients with suitable morphology for PBMV into two groups depending on the severity of MR: Group I included patients with moderate MR and Group II included patients with less than moderate MR or no MR. Patients with moderate MR were given the option of either MVR or a high-risk PBMV under MVR backup. Patients opting for PBMV were enrolled in the study after informed consent.

We performed TTE and TEE reevaluations prior to PBMV in all patients. The following parameters were reassessed: 2D-MVA, mitral diastolic gradients, extent of mitral valve calcium, extent of subvalvular pathology, and MR jet characteristics – width of vena contracta (VC), effective regurgitant orifice area (EROA), regurgitant volume (R Vol.), and regurgitant fraction (RF). A treadmill testing (TMT) using Bruce protocol was done prior to PBMV for functional assessment of the patient.

We performed coronary angiogram just prior to PBMV. Left ventricular angiogram was done just prior to and immediately after PBMV to assess the degree of MR. Pulmonary artery (PA) pressures and pulmonary capillary wedge pressures were also taken prior to the procedure.

We did PBMV following standard technique.[5] Pressure gradient across the mitral valve was measured by simultaneous pressure recordings in left atrium and left ventricle. Valvotomy was done using single balloon technique using PBMV balloon (PBMV balloon catheter set, Shenzhen Shineyard Medical Device Co Ltd., Shenzhen, China). Sizing of the balloon was done using Hung's formula[6] [patient's height in cm is rounded to nearest zero and divided by 10, and 10 is added to the ratio to yield the reference size in mm]. Initial dilatation was done using a size 1 mm less than the calculated balloon size. The need for subsequent dilatation was assessed by the operator on the basis of echocardiography and clinical examination. The reason for repeat dilatation and size of balloon was noted. Pulmonary artery pressure was measured soon after the procedure in addition to valve gradient.

Clinical and echocardiographic assessment was done within 24 h, at 1 month, and at 6 months post-procedure in Group I. Symptom status (based on New York Heart Association (NYHA) functional class) was noted and TMT was done at 6 months post-procedure for objective assessment of functional status. The primary outcome measured was a composite of cardiovascular death within 30 days of procedure, MVR within 30 days for severe MR intractable to medical management, and development of severe MR [not undergoing urgent MVR]. The secondary outcome measured was the improvement in the treadmill time (in min), NYHA functional class, and in 2D-MVA at 6 months.

3.1. Definitions

We defined severe MS as MVA $<1.5\ cm^2$. Moderate MR described MR jet with any one of the following features: VC 0.3–0.69 cm, EROA 0.20–0.39 cm^2, R Vol. 30–59 > 0.70 cm, EROA $>0.40\ cm^2$, R Vol. >60 ml/beat, and RF >50% constituted severe MR. Satisfactory improvement in MVA was defined as more than 50% of baseline value or valve area greater than $1.5\ cm^2$.

3.2. Statistical analysis

We used IBM SPSS software (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp. released 2011) for the statistical analysis. Baseline characteristics between the two groups were compared using Pearson chi-square test for significance. The composite of primary end points was calculated and compared between the two groups by Pearson chi-square test with Yates's correction for significance. The relative risk for developing severe MR was also calculated. Secondary end points were measured in the group with preexisting moderate MR and compared using Student's paired *t* test. The average improvement in the TMT time was noted. The average improvement in MVA of each patient was calculated and improvement in NYHA functional class noted. Also the degree of MR as assessed by the echocardiographic parameters [VC, EROA, R Vol., and RF] was compared between pre-BMV at 24 h after PBMV and at 6 months. A *p*-value of <0.05 was taken to be significant.

4. Results

4.1. Baseline characteristics

The study period was between February 2012 and May 2013. Fig. 1 depicts the exclusions and the final sample.

There were 17 patients in Group I and 208 in Group II. Both groups were comparable with respect to baseline characteristics, as shown in Table 1. The median Wilkins score of Group I was 7 (range 6–12).

4.2. Safety of PBMV in MS with moderate MR

All 17 patients in Group I underwent PBMV. The preprocedure and immediate post-procedure MVA were 0.886 (0.16) and 1.7 (0.28), respectively. The Mean (SD) PA systolic pressure soon after the procedure was 42.3 (12.5) mmHg. The primary outcomes at 1 month are as depicted in Table 2.

Overall, there were 2 instances of severe MR in Group I and 8 in Group II. Those in Group I who developed severe MR had Wilkins score of 12 and 11. There was one death at 30 days of PBMV, which occurred in Group II. This patient developed acute severe MR due to anterior mitral leaflet (AML) tear with severe hypotension and arterial oxygen desaturation, and died while being shifted for an emergency MVR. All patients who developed severe MR after BMV were counseled and posted for urgent or elective MVR. Three patients in Group II developed symptomatic severe MR, and underwent emergency MVR. Two patients in Group I and four patients of Group II who developed severe MR declined surgical correction and were medically managed. None of them died during the 30-day follow-up; one of these patients from Group I died after 3 months. The relative risk of developing severe MR was greater in patients with preexisting moderate MR [RR = 4.87, 95% C.I. = 1.42–16.69]. The composite of primary events was not statistically

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