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ORIGINAL ARTICLE

Immediate, early and mid-term outcomes following balloon mitral valvotomy in patients having severe rheumatic mitral stenosis with significant tricuspid regurgitation

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Abstract

Background The study examined the influence of significant tricuspid regurgitation (TR) on the immediate, early and mid-term outcomes of patients with severe mitral stenosis (MS) undergoing balloon mitral valvotomy (BMV).

Methods Among the 818 consecutive patients who underwent elective BMV in this institute from 1997 to 2003, 114 had significant TR. After propensity score–matched analysis, the data of 93 patients with significant TR were compared with the data of 93 patients who had no significant TR at the baseline. Outcomes were assessed immediately, at 1 year (early) and at 5 years (mid-term) after BMV.

Results Patients with significant TR presented more frequently with NYHA class III–IV status, atrial fibrillation (AF), severe pulmonary hypertension (PH), advanced mitral valve disease as assessed by echocardiographic score > 8, and with history of previous BMV. After propensity score–matched analysis, it was found that the immediate procedural success (54.8% vs. 58.1%, $P = 0.650$), immediate in-hospital events and prevalence of AF and heart failure at 1 year of follow-up were comparable between the two groups. At 5 years after BMV, the significant TR group had higher prevalence of heart failure and AF, greater attrition in mitral valve area (MVA) and higher pulmonary artery (PA) pressure.

Conclusions Significant TR identifies a sicker patient population with MS. Even though patients with significant TR have comparable immediate and early outcomes after BMV, they have poor outcomes on mid-term follow-up. Longer follow-up with more patients is needed to assess survival aspect of TR on patients undergoing BMV and also to look at the need for interventions to address the significant TR, apart from the mitral valve interventions.

Keywords Balloon mitral valvotomy · Tricuspid regurgitation · Procedural success · Outcome

Introduction

Balloon mitral valvotomy (BMV) has emerged as the standard therapeutic option for rheumatic mitral stenosis (MS) in selected patient population. Tricuspid regurgitation (TR) has been identified as a common accompaniment of rheumatic mitral valve disease, and moderate TR is present in about 30% of the patients with MS [1, 2]. Sagie et al. reported that patients with pre-procedural severe TR have advanced mitral valve disease, higher pulmonary vascular resistance, a lesser post-BMV mitral valve and poor long-term outcome [3, 4]. It has been shown that the accompaniment of significant TR is correlated with adverse results after mitral valve replacement (MVR) [5]. However, studies addressing the issue on patients after BMV are scarce, especially from India. Thus, the purpose of this study was to determine the influence of significant TR on the immediate, early and mid-term outcomes after BMV in a group of consecutive patients undergoing the procedure.

Methods

Study population

A retrospective analysis of clinical, echocardiography, and hemodynamic data of 818 consecutive patients, who underwent BMV in our institute from 1997 to 2003, was performed.

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There were 114 patients with significant TR and 704 patients with non-significant TR. BMVs carried out as emergency procedures under mechanical ventilation were excluded. Patients with at least moderate TR noted on echocardiogram, prior to BMV, were categorized as having significant TR. Baseline demographic data, pre-BMV echocardiography and hemodynamic data, post-BMV echocardiography and hemodynamic data, post-BMV immediate in-hospital events, and clinical (presence of heart failure and atrial fibrillation) and echocardiography data at 1 year and 5 years of follow-up subsequent to BMV were collected and analysed retrospectively.

Methodology

The retrospective study was done after obtaining ethical clearance from the Institute Ethical Committee. Informed consent was not taken due to retrospective nature of the study which was approved by SCTIMST Institute Ethics Committee.

Inclusion criteria

All consecutive BMVs done as elective procedures were included in the study.

Data (including basal demographic data, pre-BMV echocardiography and hemodynamic data, post-BMV echocardiography and hemodynamic data, post-BMV immediate in-hospital events (including peri-procedural pulmonary oedema, stroke, grade 3 or more mitral regurgitation, emergency mitral valve replacement, death), clinical data (presence of heart failure and atrial fibrillation (AF)) at 1 year and 5 years of follow-up and echocardiography data at 1 year and 5 years of follow-up) of 818 consecutive patients who underwent elective BMV in the institute from 1997 to 2003 were collected from the hospital records stored in the Medical Records Department. Among the 818 patients, it was noted in the medical reports that 114 patients had significant TR (detected by echocardiogram) prior to the BMV. For all patients, pre-BMV echocardiography was reported to be performed 24 h prior to the BMV and post-BMV echocardiography was reported to be performed 24 h after the BMV.

Exclusion criteria

BMVs carried out as emergency procedures under mechanical ventilation were excluded.

Definition of TR

Patients with at least moderate TR on echocardiogram were categorized as having significant TR. TR was assessed by careful evaluation of Doppler colour flow mapping of images of the regurgitant jet. The presence of TR was identified from the colour flow mapping display that exhibited reversed or mosaic signals originating from the tricuspid valve and extending into the right atrium during systole. The severity of regurgitation was graded as mild if the regurgitant jet area occupied < 20% of the right atrial area, as moderate if this value was between 20 and 33%, and as severe (grade 3) if this value was ≥ 34% [4].

Study groups (Fig. 1) After the propensity score–matched analysis, data of 93 patients in the significant TR group were compared with identical number in the non-significant TR group for immediate and late outcomes. The study groups assessed were patients with and without significant TR—significant TR (pre-BMV) group and non-significant TR (pre-BMV) group.

Outcomes assessed The immediate outcomes assessed included immediate procedural success which was defined as increase in mitral valve area of at least 50% from the basal or a final valve area of at least 1.5 cm^2, in the absence of more than grade 2 mitral regurgitation (MR) [6, 7], in-hospital events (including peri-procedural pulmonary oedema, stroke, grade 3 or more mitral regurgitation, emergency mitral valve replacement, death) and post-BMV hemodynamic data. The early outcomes assessed included clinical (presence of heart failure and AF) and echocardiography data at 1 year of follow-up. The mid-term outcomes assessed included clinical (presence of heart failure and AF) and echocardiography data at 5 years of follow-up. Data regarding presence or absence of heart failure was obtained from the patients' medical record. Diagnosis of AF on follow-up was based on the 12-lead electrocardiogram (ECG) at the follow-up clinic.

Statistical analysis

Statistical analysis was performed with the software SPSS version 21.0. Continuous variables were represented as mean ± SD. Unpaired Student's *t* test was used to compare procedural results. A *t* test was used to compare group means. Proportions were compared by use of the chi-square test and the Fisher exact test. Multiple logistic regression analysis was used to determine the predictors of immediate procedural success. *P* value less than 0.05 was considered significant.

Since the patients in the study were not randomized for the baseline parameters between significant and non-significant pre-BMV TR, propensity score matching of subjects with regard to baseline parameters was used to get a comparable group of patients in significant and non-significant pre-BMV TR.

Initially there were 114 patients in significant pre-BMV TR against 704 non-significant cases. But there was significant variation in baseline demographic variables and pre-BMV echocardiography and hemodynamic variables between the groups. Propensity score matching of subjects with regard to these baseline variables (basal demographic data, pre-BMV echocardiography and hemodynamic data) were used to get a comparable

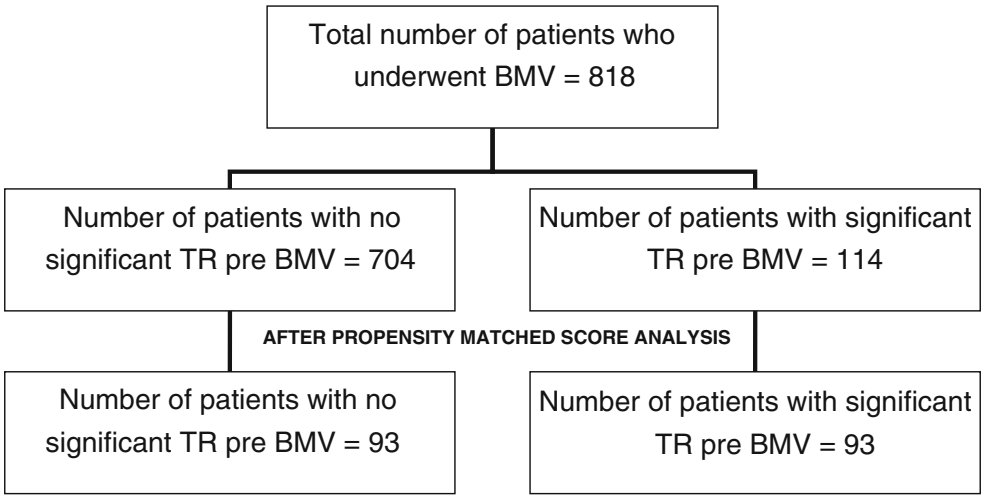

Fig. 1 Flow chart of patient selection

group of patients in significant and non-significant pre-BMV TR. Levesque's program was adapted for propensity score matching using SPSS syntax and macros. To control for these confounding influences, we conducted a propensity score analysis using the SPSS syntax and macros. In a first step, the propensity score was estimated using logistic regression. For this, we used baseline variables mentioned previously. After estimation of the propensity score, we matched participants using a simple 1:1 nearest neighbour matching. A well-balanced cohort of 93 pairs of patients, matched on the basis of propensity score, was used for the analysis.

Results

Baseline demographic data

Baseline demographic and clinical characteristics of the 2 groups of patients without propensity score–matched analysis are shown in Table 1. Patients in the significant TR group presented more frequently with NYHA functional class III and IV (47 (41.3%) vs. 242 (34.4%), $P = 0.153$), AF (19 (16.7%) vs. 76 (10.8%), $P = 0.070$) and pulmonary hypertension (PH) (102 (89.5%) vs. 315 (44.7%), $P < 0.001$). They had a higher prevalence of organic tricuspid valve involvement (18 (15.8%) vs. 6 (0.9%), $P < 0.0001$), history of previous BMV (11 (9.6%) vs. 30 (4.3%), $P = 0.016$) and echocardiographic score of > 8 (43 (37.7%) vs. 182 (25.9%), $P = 0.008$).

Baseline demographic and clinical characteristics of the 2 groups of patients after propensity score–matched analysis (93 patients in each group) are provided in Table 2.

Echocardiography data prior to BMV

Pre-BMV echocardiographic findings without propensity score–matched analysis are shown in Table 3. Patients in the significant TR group had lesser planimetry-derived mitral valve area (MVA—cm^2) (0.6 ± 0.2 vs. 0.8 ± 0.2, $P < 0.001$)

Table 1 Baseline demographic data (without propensity score–matched analysis)

	Non-significant TR (pre-BMV) group ($N = 704$)	Significant TR (pre-BMV) group ($N = 114$)	*P* value
Female (*N*, %)	544 (77.3)	96 (84.2)	0.097
Juvenile (*N*, %)	131 (18.6)	28 (24.6)	0.133
Age (*N*, %)	30.7 ± 10.6	30 ± 10.8	0.514
NYHA III/IV (*N*, %)	242 (34.4)	47 (41.3)	0.153
Atrial fibrillation (*N*, %)	76 (10.8)	19 (16.7)	0.070
Wilkin's echocardiographic score > 8 (*N*, %)	182 (25.9)	43 (37.7)	0.008
H/o. Prior closed mitral valvotomy (*N*, %)	93 (13.2)	21 (18.4)	0.137
H/o. Prior open mitral valvotomy (*N*, %)	0 (0)	1 (0.9)	0.012
H/o. Prior balloon mitral valvotomy (*N*, %)	30 (4.3)	11 (9.6)	0.016
Organic tricuspid valve disease (*N*, %)	6 (0.9)	18 (15.8)	< 0.0001
Severe pulmonary hypertension (right ventricular systolic pressure > 70 mmHg) (*N*, %)	315 (44.7)	102 (89.5)	< 0.0001

BMV balloon mitral valvotomy, *TR* tricuspid regurgitation

Table 2 Baseline demographic data (after propensity score–matched analysis)

	Non-significant TR (pre-BMV) group ($N = 93$)	Significant TR (pre-BMV) group ($N = 93$)	*P* value
Female (*N*, %)	67 (72)	77 (82.8)	0.079
Juvenile (*N*, %)	23 (24.7)	23 (24.7)	1.000
Age (*N*, %)	28.8 ± 10.1	29.9 ± 11	0.478
NYHA III/IV (*N*, %)	36 (38.7)	38 (40.9)	0.760
Atrial fibrillation (*N*, %)	11 (11.8)	13 (14)	0.660
Wilkin's echocardiographic score > 8 (*N*, %)	28 (30.1)	29 (31.2)	0.860
H/o. Prior closed mitral valvotomy (*N*, %)	13 (14)	17 (18.3)	0.427
H/o. Prior open mitral valvotomy (*N*, %)	0 (0)	1 (1.1)	0.312
H/o. Prior balloon mitral valvotomy (*N*, %)	9 (9.7)	9 (9.7)	1.0
Organic tricuspid valve disease (*N*, %)	5 (5.4)	5 (5.4)	1.000
Severe pulmonary hypertension (right ventricular systolic pressure > 70 mmHg) (*N*, %)	85 (91.4)	83 (89.2)	0.613

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and higher mean mitral valve gradient (mmHg) (18.7 ± 7.7 vs. 15.7 ± 6.6, $P < 0.01$) at the baseline.

Pre-BMV echocardiographic findings with propensity score–matched analysis are provided in Table 4. After propensity matching, both the groups had comparable planimetry-derived mitral valve area (MVA—cm^2) (0.8 ± 0.1 vs. 0.8 ± 0.2, $P < 1.000$) and mean mitral valve gradient (mmHg) (18.7 ± 8 vs. 19.2 ± 8.5, $P = 0.680$) at the baseline.

Hemodynamic data prior to BMV

Pre-BMV hemodynamic findings without propensity score–matched analysis are shown in Table 3. Patients in the significant TR group had higher left atrial (mmHg) (26.4 ± 9.8 VS. 23.2 ± 7.8, $P = 0.014$), pulmonary artery pressures (mmHg) (45.2 ± 18.1 vs. 34.4 ± 13.4, $P < 0.001$) and trans-mitral gradient (mmHg) (17 ± 6.4 VS. 15.2 ± 5.8, $P = 0.045$) prior to the BMV.

Pre-BMV hemodynamic findings with propensity score–matched analysis are provided in Table 4 which shows comparable left atrial pressure, pulmonary artery pressure and trans-mitral gradient.

Post-BMV echocardiography data

Post-BMV echocardiographic findings without propensity score–matched analysis are shown in Table 5.

Echocardiographic findings after BMV are shown in Table 6. Patients in the significant TR group had lesser planimetry-derived mitral valve area (MVA—cm^2) (1.5 ± 0.3 VS. 1.6 ± 0.3, $P = 0.024$) post BMV. However, echocardiography-derived mean mitral valve gradient (mmHg) (6.8 ± 3.8 vs. 6.8 ± 5.9, $P = 1.000$) after the intervention was not statistically significant between the two groups.

Post-BMV hemodynamic data

Post-BMV hemodynamic findings without propensity score–matched analysis are shown in Table 5.

Hemodynamic findings after BMV (after propensity scored marched analysis) are shown in Table 6. Patients in the significant TR group had higher pulmonary artery pressures (mmHg) (35.2 ± 14.2 vs. 31.3 ± 12.2, $P = 0.05$) after the BMV. The left atrial (mmHg) (15.4 ± 6.6 vs. 15 ± 5.8, $P = 0.661$) and trans-mitral gradient (mmHg) (7.6 ± 7 vs. 7.3 ±

Table 3 Pre balloon mitral valvotomy echocardiography and hemodynamic data (without propensity score–matched analysis)

	Non-significant TR (pre-BMV) group	Significant TR (pre-BMV) group	*P* value
Mitral valve area (cm^2) (by echo)	0.8 ± 0.2	0.6 ± 0.2	< 0.001
Mitral valve gradient—mean (mmHg) (by echo)	15.7 ± 6.6	18.7 ± 7.7	< 0.01
Left atrial pressure—mean (mmHg) (by catheterization)	23.2 ± 7.8	26.4 ± 9.8	0.014
Pulmonary artery pressure—mean (mmHg) (by catheterization)	34.4 ± 13.4	45.2 ± 18.1	< 0.001
Trans-mitral gradient (mmHg) (by catheterization)	15.2 ± 5.8	17 ± 6.4	0.045

BMV balloon mitral valvotomy, *TR* tricuspid regurgitation

Table 4 Pre balloon mitral valvotomy echocardiography and hemodynamic data (after propensity score–matched analysis)

	Non-significant TR (pre-BMV) group	Significant TR (pre-BMV) group	*P* value
Mitral valve area (cm^2) (by echo)	0.8 ± 0.2	0.8 ± 0.1	1.000
Mitral valve gradient—mean (mmHg) (by echo)	19.2 ± 8.5	18.7 ± 8	0.680
Left atrial pressure—mean (mmHg) (by catheterization)	25.6 ± 6.6	26.4 ± 10.1	0.523
Pulmonary artery pressure—mean (mmHg) (by catheterization)	45.3 ± 15.7	44.8 ± 18.2	0.841
Trans-mitral gradient (mmHg) (by catheterization)	17 ± 5.5	16.7 ± 6.3	0.730

BMV balloon mitral valvotomy, *TR* tricuspid regurgitation

6.6, $P = 0.764$) after the intervention were not statistically significant between the two groups.

Immediate post-BMV in-hospital events

In-hospital events are shown in Table 7. There was no difference between the two groups regarding immediate procedural success (54.8% vs. 58.1%, $P = 0.650$) and acute complications including peri-procedural pulmonary oedema, stroke, grade 3 or more mitral regurgitation, emergency mitral valve replacement or death.

Predictors of immediate procedural success

Multiple logistic regression analysis (without any restriction imposed on analysis) has shown that atrial fibrillation, Wilkins echocardiographic score and pre-procedural mitral valve area, and not significant TR, were the only predictors of immediate procedural success (Table 8).

Follow-up data at 1 year after BMV

Data of 88 patients in the significant TR group and data of 89 patients in the non-significant TR group were available at 1 year of follow-up. The occurrence of heart failure (1 (1.1%) vs. 1 (1.1), $P = 1.000$) and AF (12 (13.6%) vs. 11 (12.4), $P = 0.812$) were comparable between the study groups at 1 year of follow-up. The significant TR group had lesser MVA (cm^2) (1.5 ± 0.3 vs. 1.6 ± 0.2, $P = 0.009$) (Table 9). Mean mitral valve gradient (mmHg) (7.1 ± 5.3 vs. 6.2 ± 3.3, $P = 0.176$) was comparable between the two groups. The pulmonary artery systolic pressure (mmHg) (51.5 ± 15.3 vs. 44.8 ± 11.6, $P = 0.001$) was higher in the significant TR group.

Follow-up data at 5 years after BMV

A total of 83 patients each in the significant TR group and the non-significant TR group were alive at 5 years of follow-up. There was no death in the non-significant TR group and 2 deaths in the significant TR group. Mortality was too small to analyse for significance. Remaining patients were lost to follow-up.

The occurrence of heart failure (12 (14.5%) vs. 4 (4.8%), $P = 0.035$) and AF (25 (30.2%) vs. 14 (16.9%), $P = 0.044$) were significantly higher in patients in the significant TR group. The significant TR group had lesser MVA (cm^2) (1.3 ± 0.3 vs. 1.5 ± 0.3, $P = 0.001$) (Table 10), greater mean mitral valve gradient (mmHg) (8.1 ± 4.8 vs. 6.7 ± 3.5, $P = 0.033$) and pulmonary artery systolic pressure (mmHg) (45.8 ± 13.7 vs. 41.2 ± 13, $P = 0.028$) at 5 years of follow-up post BMV.

Discussion

The pathogenesis of TR in mitral valve disease is multifaceted. Most often, TR is functional, secondary to right ventricle dilation and dysfunction and tricuspid annular dilation, as a consequence of pulmonary hypertension. Increased left atrial size and pressure might result in atrial fibrillation, which in turn causes right atrial dilatation leading to further tricuspid

Table 5 Post balloon mitral valvotomy echocardiography & hemodynamic data (without propensity score–matched analysis)

	Non-significant TR (pre-BMV) group	Significant TR (pre-BMV) group	*P* value
Mitral valve area (cm^2) (by echo)	1.6 ± 0.3	1.5 ± 0.3	0.024
Mitral valve gradient—mean (mmHg) (by echo)	6.1 ± 3.6	7 ± 3.8	0.099
Left atrial pressure—mean (mmHg) (by catheterization)	14.2 ± 5.7	15.5 ± 6.4	0.145
Pulmonary artery pressure—mean (mmHg) (by catheterization)	25 ± 10.1	35.2 ± 14.5	< 0.0001
Trans-mitral gradient (mmHg) (by catheterization)	6.3 ± 4.6	7.6 ± 6.6	0.152

BMV balloon mitral valvotomy, *TR* tricuspid regurgitation

Table 6 Post balloon mitral valvotomy echocardiography and hemodynamic data (after propensity score–matched analysis)

	Non-significant TR (pre-BMV) group	Significant TR (pre-BMV) group	*P* value
Mitral valve area (cm^2) (by echo)	1.6 ± 0.3	1.5 ± 0.3	0.024
Mitral valve gradient—mean (mmHg) (by echo)	6.8 ± 5.9	6.8 ± 3.8	1.000
Left atrial pressure—mean (mmHg) (by catheterization)	15 ± 5.8	15.4 ± 6.6	0.661
Pulmonary artery pressure—mean (mmHg) (by catheterization)	31.3 ± 12.2	35.2 ± 14.2	0.05
Trans-mitral gradient (mmHg) (by catheterization)	7.3 ± 6.6	7.6 ± 7	0.764

BMV balloon mitral valvotomy, *TR* tricuspid regurgitation

annular dilation and TR. In patients with rheumatic valve disease, TR may also be caused by organic tricuspid valve (TV) involvement. There is increased relevance of clinical recognition of the presence, aetiology and severity of TR associated with mitral stenosis, because it affects the outcome of mitral valve surgery [2]. The degree of resolution of significant TR after correction of mitral stenosis is not always predictable. Patients undergoing BMV constitute a unique patient group, which can allow us to evaluate the impact of significant TR in hemodynamically significant mitral stenosis.

Less information is available as to whether significant TR is associated with adverse outcome of BMV, especially among Indian patients. In the present study, we found that 13.9% of the patients with hemodynamically significant mitral stenosis undergoing BMV had associated significant TR. Sagie et al. have reported that 31% of patients undergoing BMV had moderate or severe TR at the baseline [3, 4]. The present study identifies that patients with rheumatic severe mitral stenosis with significant TR belong to a sicker subset of patient population and baseline significant TR is associated with poorer mid-term outcomes, despite comparable immediate and early outcomes after BMV.

Demographic factors and immediate procedural success

The patients with rheumatic severe mitral stenosis with significant TR at baseline were relatively sicker and had more advanced mitral valve disease as suggested by the higher incidence of atrial fibrillation (19 (16.7%)), heart failure (47 (41.3%)), deformed mitral valve with higher Wilkin's echocardiographic score (11 (9.6%)), history of prior balloon mitral interventions (11 (9.6%)) and pulmonary hypertension (102 (89.5%)). They also had lower mitral valve area, higher trans-mitral gradient and higher left atrial and pulmonary artery pressures at the baseline. These suggest that accompanying significant TR with severe mitral stenosis is associated with poorer baseline clinical status. Higher Wilkin's echocardiographic score suggests more extensive structural and functional disease of the mitral valve apparatus. The poorer baseline clinical status in the group with severe TR may reflect a combination of more advanced mitral disease as well as hemodynamically important TR associated with pulmonary hypertension. Multiple logistic regression analysis has shown that atrial fibrillation, Wilkins echocardiographic score and pre-procedural mitral valve area and not significant TR were the only predictors of immediate procedural success. Significant TR identifies a sicker population of MS patients with higher occurrence of heart failure and atrial fibrillation. Our observation is consistent with previous studies, which have noted a similar association [2, 8].

Because of the baseline differences in the study population (patients with and without significant TR), a propensity score–matched analysis was done for comparing the immediate procedural success, in-hospital complications and clinical outcome at 1 year and 5 years after BMV. It was seen that after

Table 7 Post balloon mitral valvotomy immediate In-hospital events (after propensity score–matched analysis)

	Non-significant TR (pre-BMV) group	Significant TR (pre-BMV) group	*P* value
Immediate procedural success, *N* (%)	54 (58.1)	51 (54.8)	0.650
Peri-procedural pulmonary oedema, *N* (%)	3 (3.2)	2 (2.2)	0.674
Stroke, *N* (%)	1 (1.1)	1 (1.1)	1.000
Emergency mitral valve replacement, *N* (%)	2 (2.2)	3 (3.2)	0.674
Mortality, *N* (%)	0 (0)	0 (0)	-
Grade 3 or more mitral regurgitation, *N* (%)	12 (12.9)	8 (8.6)	0.344

BMV balloon mitral valvotomy, *TR* tricuspid regurgitation

Table 8 Independent predictors of immediate procedural success by multiple logistic regression

	B	S.E.	*p*	Ratio after odds (95% CI)
Atrial fibrillation	0.85	0.25	0.001	2.34 (1.44–3.79)
Wilkin's echocardiographic score > 8	0.82	0.17	0.000	2.26 (1.61–3.17)
Pre-procedural mitral valve area	1.28	0.57	0.025	3.58 (1.17–10.98)

the propensity score–matched analysis, the immediate procedural success (54.8% vs. 58.1%, $P = 0.650$) and in-hospital complications were comparable between the study groups. But the absolute immediate post-BMV mitral valve area and the post-BMV pulmonary artery pressure were significantly higher in those patients who had significant TR. Our observation is also consistent with the previous studies in that patients with significant TR have lesser increase in the MVA after BMV [4, 8, 9]. It has been shown that the long-term outcomes following BMV are primarily driven by the absolute post-BMV mitral valve area and hence lesser post-BMV mitral valve area in the significant TR group is an important concern. Apart from the operator trying to reduce the risk of significant procedural mitral regurgitation by allowing checked balloon dilatation, it may also be possible that with significant TR, the atria might have been dilated in those patients which might have posed some technical difficulties in ensuring an optimal balloon dilatation subsequently resulting in a lower post-BMV mitral valve area in patients with significant TR.

Most of the studies assessing the influence of TR on BMV are from the west. In these studies, patients with TR were identified as a sicker population. That means even prior to intervention, they were sicker and comparison was made between relatively sicker patients with TR and patients with non-significant TR. Therefore, these patients have different denominators, even at the baseline, which might have altered the outcome. Our study is unique in that we have done a propensity matching analysis to match the denominators.

After propensity matching, we noted that the immediate procedural success (54.8% vs. 58.1%, $P = 0.650$) was comparable between those with and without significant TR at the baseline. The point to be noted is that, even if the procedural success is comparable between the index study groups, it is well below immediate procedural success rates reported (90 to 97%) in other series involving all the subsets [7, 10–12].

TR and in-hospital events

The incidence of in-hospital complications including peri-procedural pulmonary oedema, stroke, mitral regurgitation of grade 3 or more, emergency mitral valve replacement and mortality was comparable among the study groups.

TR and follow-up at 1 year after BMV

The occurrence of heart failure and atrial fibrillation at 1 year post BMV was comparable between the study groups. Patients with significant TR had lesser mitral valve area on 1-year follow-up with lesser regression of mean mitral valve gradient and pulmonary artery systolic pressure. Persistence of high pulmonary artery pressure at 1 year of follow-up in the significant TR group, despite a mitral valve area of 1.5 ± 0.3 cm^2, probably indicates underlying pulmonary vascular disease [13, 14].

TR and follow-up at 5 years after BMV

Negative impact of significant unaddressed TR on long-term survival has been highlighted in many Western series [15–18]. In our study, at 5 years after BMV, there was no death in the non-significant TR group and 2 deaths in the significant TR group. Mortality was too small to be analysed for significance.

Studies from India are scarce. Our study agrees with other studies in that patients with significant TR undergoing BMV are associated with poor outcomes in the form of higher prevalence of AF and heart failure. They also had greater attrition

Table 9 Follow-up at 1 year (after propensity score–matched analysis)

	Non-significant TR (pre-BMV) group ($N = 89$)	Significant TR (pre-BMV) group ($N = 88$)	*P* value
Mitral valve area (cm^2)	1.6 ± 0.2	1.5 ± 0.3	0.009
Mitral valve gradient—mean (mmHg)	6.2 ± 3.3	7.1 ± 5.3	0.176
Pulmonary artery systolic pressure (mmHg)	44.8 ± 11.6	51.5 ± 15.3	0.001
Heart failure, *N* (%)	1 (1.1)	1 (1.1)	1.000
Atrial fibrillation, *N* (%)	11 (12.4)	12 (13.6)	0.812

BMV balloon mitral valvotomy, *TR* tricuspid regurgitation

Table 10 Follow-up at 5 years (after propensity score–matched analysis)

	Non-significant TR (pre-BMV) group ($N = 83$)	Significant TR (pre-pre-BMV) group ($N = 83$)	P value
Mitral valve area (cm^2)	1.5 ± 0.3	1.3 ± 0.3	< 0.001
Mitral valve gradient—mean (mmHg)	6.7 ± 3.5	8.1 ± 4.8	0.033
Pulmonary artery systolic pressure (mmHg)	41.2 ± 13	45.8 ± 13.7	0.028
Heart failure, N (%)	4 (4.8)	12 (14.5)	0.035
Atrial fibrillation, N (%)	14 (16.9)	25 (30.2)	0.0441

BMV balloon mitral valvotomy, *TR* tricuspid regurgitation

in the mitral valve area. Apart from that, pulmonary artery pressure persisted to be higher in them.

These observations tend us to believe that patients with mitral stenosis and significant TR represent a unique problem and addressing mitral stenosis alone may not be enough in improving the long-term outcomes. Longer follow-up with more number of patients is needed to throw light on survival aspect of TR on patients undergoing BMV and also to look at the need for interventions to address the significant TR apart from the mitral valve interventions.

Conclusion

Significant tricuspid regurgitation identifies a sicker population of rheumatic severe mitral stenosis patients with higher prevalence of heart failure, atrial fibrillation and pulmonary hypertension. Even though patients with significant tricuspid regurgitation have comparable immediate and early outcomes after balloon mitral valvotomy, they have poor outcomes on mid-term follow-up with respect to higher occurrence of heart failure, atrial fibrillation and adverse hemodynamics.

Limitations

Limitations of our study include a small sample size, no randomisation and no control group. Selection bias would have played a role, where only patients who required BMV and were fit to do so would be offered the intervention. Patients included only represent the interventional arm, which is BMV, with no direct comparators. We do acknowledge that we could not provide any information regarding the length of hospital stay, renal impairment or need for inotropic support. The short follow-up duration is a major limitation. Diagnosis of AF on follow-up was based on the ECG at the follow-up clinic. It is possible that paroxysmal AF was missed. Longer follow-up with greater number of patients would have been ideal in addressing mortality benefits. Because of the retrospective nature of the study and the fact that the data is a reflection of a single-centre experience, further analysis with a larger cohort and multiple centres and longer follow-up are needed in future.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Research involving human participants and/or animals We confirm that the retrospective study was approved by the SCTIMST Institute Ethics Committee and certify that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

Informed consent Informed consent was not taken due to retrospective nature of the study which was approved by SCTIMST Institute Ethics Committee.

Ethical approval Retrospective study approved by SCTIMST Institute Ethics Committee.

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