

Demographic, Clinical and Echocardiographic Characteristics of Patients with Rheumatic Mitral Stenosis Treated with Mitral Balloon Valvuloplasty Procedure: A Local Experience

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Abstract

Objectives: Rheumatic mitral stenosis (RMS) remains a significant health challenge, particularly in low- and middle-income countries, due to limited access to preventive measures and timely treatment. Percutaneous mitral balloon valvuloplasty (PMBV) has become the preferred treatment for RMS, offering a less invasive alternative to surgical mitral valve replacement. This study aimed to evaluate the demographic, clinical, and echocardiographic characteristics of patients with RMS undergoing PMBV and to assess the procedural outcomes.

Materials and Methods: This study included 52 patients who underwent PMBV RMS. Patients with non-RMS, incomplete patient files, or previous valve surgeries were excluded.

Results: The procedural success rate was 87%, with better outcomes observed in patients with a Wilkins score ≤ 8 than in those with a score > 8 . PMBV resulted in a significant increase in mitral valve area (MVA) (from 1.18 ± 0.19 cm² to 2.27 ± 0.48 cm², $p=0.001$) and a decrease in both mean mitral valve gradient (from 12.82 ± 3.5 mmHg to 5.97 ± 2.04 mmHg, $p=0.001$) and maximum mitral valve gradient (from 27.12 ± 14.0 mmHg to 12.70 ± 3.1 mmHg, $p=0.001$). Although the



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Abstract

procedure was generally safe, manageable complications, such as chordal rupture (1 case, 1.9%) and mitral regurgitation (MR) progression, were observed, particularly in patients with higher Wilkins scores.

Conclusion: The significant improvements in MVA and reduced gradient observed in our study underscore the effectiveness of PMBV, even in patients with higher Wilkins scores. Although we observed manageable complications, such as chordal rupture and MR progression, the overall safety and efficacy of PMBV in our patient population highlight its value as a practical and effective treatment option for RMS in our clinical setting. These findings support the continued use of PMBV as a standard treatment approach in our region, potentially enhancing the quality of care for patients with this condition.

Keywords: Balloon valvuloplasty, gradient mitral, stenosis, percutaneous, rheumatic, Wilkins scores

Introduction

It remains a major challenge for global health that the burden of rheumatic heart disease (RHD) persists, especially in low- and middle-income countries where access to preventive measures and timely treatment is often limited. The severe morbidity and mortality of this disease, which affects millions of people worldwide, are due to complications arising from acute rheumatic fever. Among its various manifestations, rheumatic mitral stenosis (RMS) is particularly significant because of its potential to impair cardiac function, leading to congestive heart failure, atrial fibrillation (AF), and other life-threatening conditions^(1,2).

Percutaneous mitral balloon valvuloplasty (PMBV) has become the cornerstone treatment of choice for RMS, offering a less invasive alternative to surgical valve replacement. It not only alleviates symptoms associated with mitral valve obstruction but also improves overall patient outcomes^(3,4). Given the dynamic epidemiology of RHD and evolving therapeutic modalities, extensive research on the long-term outcomes and efficacy of PMBV in patients with RMS is warranted. Understanding the characteristics of these patients and the success rates of these procedures is critical for optimizing treatment strategies and improving the quality of care provided to these patients^(5,6).

To bridge the existing knowledge gap, our study aims to provide detailed information on these issues by conducting a comprehensive evaluation of individuals diagnosed with RMS who have undergone PMBV in our cardiology clinic. This research not only provides insight into patient outcomes after PMBV but also elucidates the long-term effects of PMBV in our regional setting^(7,8).

Our research aims to analyze the demographic, clinical, and echocardiographic features of this patient group and to study their post-valvuloplasty outcomes. The findings will hopefully contribute significantly to the understanding of this condition, guiding clinical practice and laying the groundwork for future research on improved therapeutic strategies for RMS⁽⁹⁾. Furthermore, by identifying prevalent risk factors and patient profiles most likely to benefit from PMBV, the study will help develop individualized treatment plans that address the specific needs of these patients⁽¹⁰⁾.

In summary, RMS, which is characterized by significant morbidity and mortality, urgently requires research focusing on management approaches, such as PMBV. Therefore, based on a comprehensive analysis of patient records, our study contributes to a better understanding of the outcomes associated with treatment interventions in RMS, thereby enabling improvements in healthcare and medical practice.

Materials and Methods

This retrospective study was conducted at our cardiology clinic. The medical history and demographic characteristics of the patients were obtained from the hospital data. Transesophageal echocardiography (TEE) was performed in all patients before the procedure. Patients with an asymptomatic valve area greater than 1.5 cm², moderate to severe mitral regurgitation (MR) (3+, 4+), other valvular pathologies or coronary artery disease requiring surgery, left atrial thrombus seen through TEE, or a Wilkins score >12 were excluded.

From an initial cohort of 63 patients with symptomatic RMS evaluated for PMBV, 9 patients were excluded due to the following contraindications: mitral valve area (MVA) >1.5 cm²; moderate or severe MR; extensive calcification of both commissures; absence of commissural fusion; significant aortic and tricuspid valve disease requiring surgery; or concurrent coronary artery disease requiring coronary artery bypass grafting. Additionally,

two more patients were excluded from the analysis due to missing or unreliable data, resulting in a final sample size of 52 subjects (Figure 1).

Echocardiography: Echocardiography was performed with a Vivid S6 echocardiography machine (GE-Vingmed Ultrasound, Horten, Norway) using 2.5 MHz transthoracic and 6 MHz transesophageal probes, according to the American Society of Echocardiography guidelines. Different measurements were performed three times to enhance the accuracy. Parasternal long-axis views, apical four-chamber views, and M-mode 2-D echo Doppler were taken into consideration for evaluation. Pulsed-wave Doppler analysis was also employed in conjunction with continuous-wave Doppler methods. The other methods used include planimetry for measuring MVA and pressure half-time techniques. The morphological characteristics of the mitral valve were classified using the Wilkins scoring system, ranging from 1 to 16 points, with patients scoring ≤12 considered suitable for the procedure.

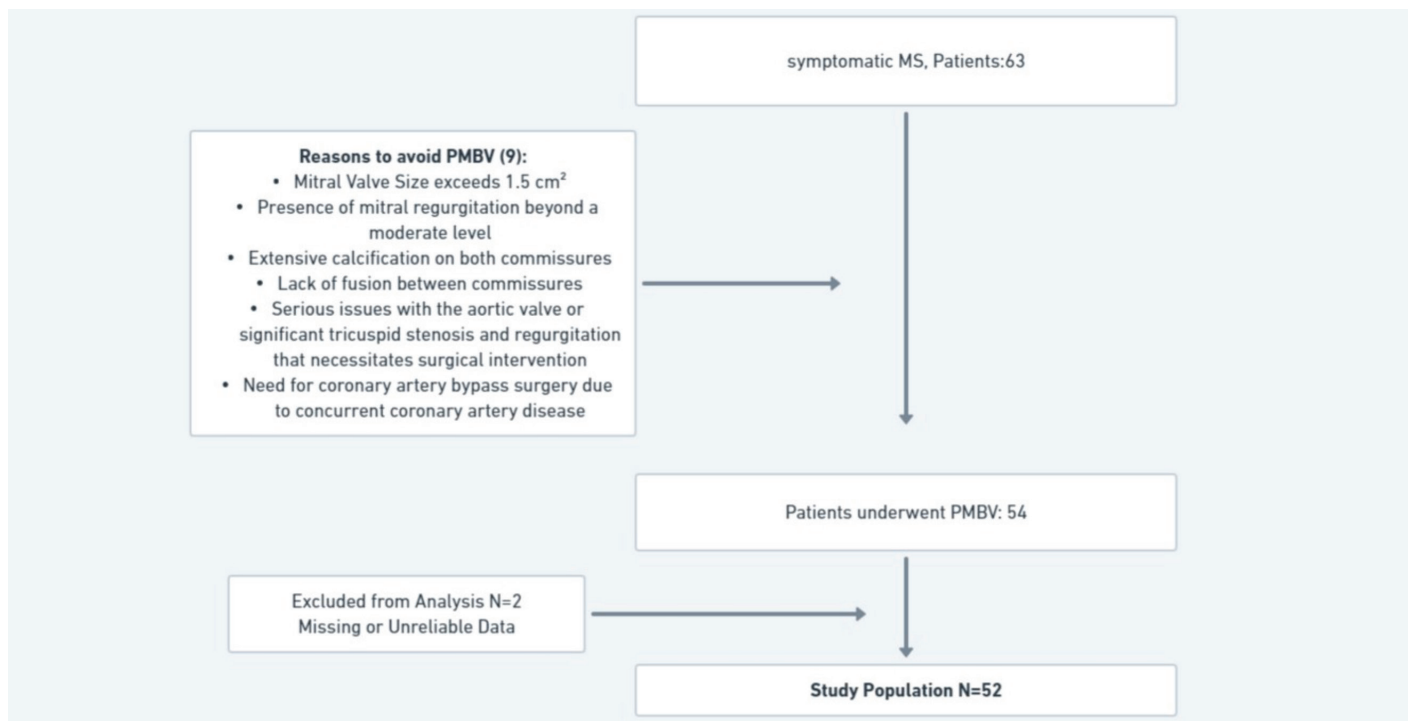


Figure 1. Study design

PMBV: Percutaneous mitral balloon valvuloplasty, MS: Mitral stenosis

All patients underwent TEE before the operation to exclude left atrial thrombus, evaluate mitral valve morphology and regurgitation, and establish other major cardiac pathologies.

PMBV: PMBV was performed under local anesthesia using a trans-septal approach through the right femoral vein. TTE monitoring was performed during and after the procedure. Hemodynamic measurements were performed intraoperatively. The Inoue balloon system (Toray Industries Inc, Tokyo, Japan) was used throughout the experiment, and the balloon size was determined at the discretion of the operator. The procedure was terminated if a commissural tear, significant increase in mitral valve area, significant decrease in mitral valve gradient, or the development of moderate-to-severe MR was detected during the procedure. Procedural success was defined as a 50% increase in MVA compared with the pre-procedural value and/or an (MVA) $>1.5 \text{ cm}^2$, with no development of MR grade 3+ or 4+.

Follow-up: Clinical follow-up and echocardiographic evaluation were performed before the intervention, within 24-48 hours after the intervention, at 3-6-month intervals, and then annually thereafter. Successful endpoints were defined similarly to procedural success criteria, with respect to significant improvement in MVA without the appearance of severe MRs.

Statistical Analysis

Statistical analysis was performed using SPSS software. Continuous variables were presented as mean \pm standard deviation and categorical variables expressed as absolute frequencies (n) or percentages (%). Trend analysis used the Cochran-Armitage test, with a significance level set at $p < 0.05$.

This methodological approach ensured a comprehensive assessment of the PMBV results, adhering to ethical standards, and ethics committee approval was obtained from the Van Yüzüncü Yıl Non-Interventional Clinical Research Ethics Committee (approval no.: 2019/10/11 date: 24.05.2019). Informed consent was obtained from

all participants, ensuring their voluntary participation and confidentiality.

Results

Our research enrolled 52 consecutive patients (36 females, 16 males; mean age 48 ± 13 years; range 24 to 76 years, Table 1) who underwent PMBV for symptomatic RMS with a valve area $\leq 1.5 \text{ cm}^2$. The procedural success rate was 87%, which was higher in patients with a Wilkins score ≤ 8 (90%) than in those with a Wilkins score > 8 (80%). Of the 7 unsuccessful procedures, 3 were in subjects with low Wilkins scores, and 4 were in subjects with high Wilkins scores. Furthermore, there were 8 patients with AF, with 2 in the Wilkins ≤ 8 group and 6 in the Wilkins > 8 group, indicating that older individuals might be more susceptible to AF, possibly leading to increased AF among patients with a Wilkins score > 8 ($p = 0.001$) (Table 2). The distribution of study subjects into different New York Heart Association classes revealed significant diversity in preprocedural functional status, reflecting the echocardiographic and demographic variations observed between the Wilkins score groups. Notably, the left ventricular internal diameter at end-diastole (LVIDd) was significantly larger in the Wilkins > 8 group ($5.35 \pm 0.85 \text{ cm}$) than in the Wilkins ≤ 8 group ($4.93 \pm 0.52 \text{ cm}$) ($p = 0.035$), and the left atrium (LA) size was also greater in the Wilkins > 8 group ($4.82 \pm 0.63 \text{ cm}$) than in the Wilkins ≤ 8 group ($4.44 \pm 0.51 \text{ cm}$) ($p = 0.025$). Additionally, the left atrial area was significantly larger in patients with a Wilkins score > 8 ($30 \pm 5.74 \text{ cm}^2$) compared to those with a Wilkins score ≤ 8 ($25.37 \pm 4.36 \text{ cm}^2$) ($p = 0.001$) (Table 2).

Baseline demographic and echocardiographic characteristics before RMS revealed important insights into the structural heart changes associated with RMS in this population. The study population was divided according to the previously mentioned PMBV determinant, Wilkins score. The left ventricular ejection fraction for those with a lower score of ≤ 8 was $64.88 \pm 3.34\%$ compared to $62.90 \pm 4.86\%$ in the Wilkins

score >8 subgroup, with no statistical difference between them ($p=0.89$). However, significant differences in LVIDd were observed between patients with a Wilkins score >8 (5.35 ± 0.85 cm) and those with a Wilkins score ≤ 8 (4.93 ± 0.52 cm), indicating severe dilatation ($p=0.035$). Furthermore, the larger LA size in the Wilkins score ≤ 8 group was smaller than that in the Wilkins score >8 group, suggesting that long-standing MR alters the geometry of the atria over time ($p=0.025$)⁽¹⁰⁾. These differences in baseline characteristics reflect the higher echocardiographic burden in patients with higher Wilkins scores, which calls for a more thorough preprocedural evaluation to predict PMBV outcomes (Table 2).

Post-procedure TTE measurements, as shown in Table 3, clearly demonstrate the effectiveness of PMBV in our study cohort. The procedure resulted in a significant increase in MVA from 1.18 ± 0.19 cm² before to 2.27 ± 0.48 cm² after PMBV in all subjects treated ($p=0.001$). This change was consistent and significant between the two groups: Wilkins score ≤ 8 and Wilkins score >8, thereby confirming the broad efficacy of PMBV. More specifically, MVA increased significantly from 1.26 ± 0.16 cm² to 2.47 ± 0.43 cm² in those with scores ≤ 8 , and from 1.05 ± 0.16 cm² to 1.95 ± 0.35 cm² in those with scores >8⁽¹¹⁾.

Furthermore, the mean gradient (MeanG) and maximum gradient (MaxG) through the mitral valve

Table 1. Preoperative characteristics of patients in terms of age and functional capacity

Parameter	n	Total (Mean \pm SD)	Wilkins ≤ 8 (n=32) (Mean \pm SD)	Wilkins >8 (n=20) (Mean \pm SD)
Gender	52	48 \pm 13	40 \pm 10	61 \pm 8
Male	16	53 \pm 11	44 \pm 10	61 \pm 15
Female	36	46 \pm 14	38 \pm 23	62 \pm 10
NYHA class I	0	-	-	-
NYHA class II	20	-	18	2
NYHA class III	27	-	12	15
NYHA class IV	5	-	2	3

NYHA: New York Heart Association, SD: Standard deviation

Table 2. Preoperative baseline echocardiographic and demographic characteristics of patients

Parameter	Wilkins ≤ 8 (n=32)	Wilkins >8 (n=20)	p-value
LVEF	64.88 \pm 3.34	62.90 \pm 4.86	0.89
LVIDd	4.93 \pm 0.52	5.35 \pm 0.85	0.035
LVIDs	3.92 \pm 0.44	4.00 \pm 0.59	0.565
LA	4.44 \pm 0.51	4.82 \pm 0.63	0.025
LAarea	25.37 \pm 4.36	30 \pm 5.74	0.001
sPAB	49.25 \pm 7.26	48.7 \pm 9.10	0.811
HR	85 \pm 10	83 \pm 12	0.511
AF	2	6	0.001
HT	4	3	-
DM	4	4	-
Coronary artery disease	2	3	-
Smoking	11	5	-
Cerebrovascular events	0	1	-
Pregnancy	2	0	-

LVEF: Left ventricular ejection fraction, LVIDd: Left ventricular internal diameter at end-diastole, LA: Left atrium, LAarea: Left atrial area, sPAB: Systolic pulmonary artery pressure, HR: Heart rate, AF: Atrial fibrillation, HT: Hypertension, DM: Diabetes mellitus

decreased considerably, suggesting a post-PMBV improvement in blood flow and reduction in cardiac workload⁽¹²⁾. After the procedure, significant decreases in pulmonary hypertension were observed, indicating that PMBV can be successfully used to correct RMS regardless of the initial Wilkins score, leading to better clinical outcomes and improved quality of life for these patients (Table 3).

Comparative laboratory values before and after PMBV treatment demonstrate the systemic effects of this cardiac intervention. The total white blood cells (WBC) count slightly decreased from 7913±2186 cells/μL to 7528±2588 cells/μL, indicating a non-significant systemic inflammatory response following PMBV. Consequently, total neutrophil counts within the WBC decreased from 4940±2012 to 4589±2053. There were minimal variations in lymphocyte counts, implying that the procedure had an insignificant effect on systemic inflammation. The relationship between these two types of blood cells remained relatively stable, indicating no

significant effect on overall health after surgery. The serum levels of C-reactive protein and creatinine remained stable, indicating that systemic safety was not affected by the procedure. Thyroid stimulating hormone (TSH) levels did not change after PMBV, indicating normal thyroid function. Overall, these findings demonstrated the procedural safety of PMBV without significant systemic inflammatory markers or organ dysfunction (Table 4).

Our research aimed to identify hospital situations and outcomes during 1-month follow-up after PMBV. The primary objective of this study was to evaluate treatment outcomes and safety measures with respect to certain conditions that occur while patients are still hospitalized or during the first 4 weeks after the PMBV procedure. Data from each patient was recorded using a data collection form designed by the researcher. A total of 52 patients were included in the analysis; they were stratified into two groups based on Wilkins scores: ≤8 (32 patients) and >8 (20 patients). There was an increase in MR in one patient per group, which may indicate a potential worsening of

Table 3. Changes in echocardiographic parameters before and after PMBV

Parameter	Pre PMBV (Total)	Post PMBV (Total)	p-value	Pre PMBV Wilkins ≤8	Post PMBV Wilkins ≤8	Pre PMBV Wilkins >8	Post PMBV Wilkins >8	p-value
MVA, cm ² (planimetric)	1.18±0.19	2.27±0.48	0.001	1.26±0.16	2.47±0.43	1.05±0.16	1.95±0.35	0.001
MeanG, mmHg	12.82±3.5	5.97±2.04	0.001	12.87±4.0	5.82±2.04	12.73±2.9	6.20±1.72	0.521
MaxG, mmHg	27.12±14.0	12.70±3.1	0.001	28.25±18.19	12.16±3.43	25.32±6.60	13.55±2.57	0.127
PHT (cm ²)	1.18±0.19	2.26±0.44	0.001	1.25±0.16	2.43±0.42	1.07±0.19	1.98±0.33	0.01
sPAB (mmHg)	49±8	33±11	0.001	48±9	32±9	50±7	35±12	0.811

PMBV: Percutaneous mitral balloon valvuloplasty, MVA: Mitral valve area, MeanG: Mean gradient, MaxG: Maximum gradient, PHT: Pulmonary hypertension, sPAB: Systolic pulmonary artery pressure

Table 4. Changes in laboratory values before and after PMBV

Parameter	Pre-procedure	Post-procedure	p-value
WBC (cells/μL)	7913±2186	7528±2588	p>0.05
Neutrophil (cells/μL)	4940±2012	4589±2053	p>0.05
Lymphocyte (cells/μL)	2014±724	2292±868	p>0.05
N/L ratio	2.56±1.42	2.6±2.37	p>0.05
CRP (mg/L)	8.22±11.26	16.08±35.198	p>0.05
Creatinine (mg/dL)	0.80±0.16	0.82±0.19	p>0.05
TSH (μIU/mL)	5.19±16.23	5.27±12.68	p>0.05

PMBV: Percutaneous mitral balloon valvuloplasty, WBC: White blood cells, CRP: C-reactive protein, TSH: Thyroid stimulating hormone, N: Neutrophils, L: Lymphocyte

valve function after PMBV. During follow-up, three mitral valve replacements were performed, all in the higher Wilkins score category, highlighting the increased procedural difficulty and risk in patients with severe mitral stenosis (MS). Minor complications, such as groin hematomas, were evenly distributed between the groups, without any major adverse cardiovascular events, strokes, or procedure-related deaths, indicating the overall safety and effectiveness of PMBV in these patients (Table 5).

The results of our investigation clearly indicate the safety and efficacy of PMBV as a treatment option for patients with RMS. PMBV improved MVA in various categories of patients with different levels of disease severity, according to their Wilkins scores, with a success rate of up to 87%. Significantly, the intervention led to considerable reductions in both MeanG and MaxG across the mitral valve, indicating decreased cardiac workload and improved blood flow. The stability of laboratory values after the procedure further signifies minimal systemic impact, demonstrating PMBV's safety from this perspective. Although some manageable complications did arise, it should be emphasized that no major adverse events, including procedure-related deaths, were recorded, thus proving PMBV's validity as an alternative method for managing RMS. These findings suggest that PMBV could be used as a standard treatment for patients with

RMS, opening the door to further research and wider clinical application.

Discussion

The results of this study support the use of PMBV as a highly effective and safe method for treating RMS. This procedure significantly improves echocardiographic parameters and has high procedural success rates. Stable laboratory values after PMBV indicate that the procedure is less invasive than surgery, thereby ensuring safety and alleviating concerns about potential systemic complications. The serum levels of C-reactive protein and creatinine remained stable, indicating that systemic safety was not affected by the procedure. TSH levels did not change after PMBV, indicating normal thyroid function. The findings of this study demonstrate PMBV safety profile, given the absence of major adverse events and the manageable nature of the observed complications. This makes PMBV a compelling option for both physicians and patients, emphasizing its role in improving patient outcomes and quality of life for patients with RMS^(12,13).

Research on PMBV in patients with RMS demonstrated high efficacy and safety, with significant improvements in MVA and reductions in mean and maximum mitral valve gradients across different Wilkins score categories.

Table 5. In-hospital and short-term follow-up events

Parameter	Total	Wilkins ≤8	Wilkins >8
Number of patients	52	32	20
Chordal rupture	1	-	1
Emergency MVR	1	-	1
Advanced MR	2	1	1
Total MVR (12±6 months follow-up)	3	-	3
Mild pericardial effusion	2	1	1
Stroke	1	1	-
Groin hematoma	2	1	1
Unsuccessful PMBV	7	3	4
MACE	1	0	1

MVR: Mitral valve replacement, MR: Mitral regurgitation, PMBV: Percutaneous mitral balloon valvuloplasty, MACE: Major adverse cardiac events- mitral valve replacement

However, complications such as chordal rupture (1 case, 1.9%) and progression to higher-degree MR were observed, particularly among patients with higher Wilkins scores. These baseline differences reflect the greater echocardiographic burden in patients with higher Wilkins scores, highlighting the need for a thorough preprocedural evaluation to predict PMBV outcomes. Additionally, the occurrence of AF in 8 patients, particularly older individuals who are more susceptible, suggests an increased incidence of AF in patients with a Wilkins score >8. These findings highlight the importance of careful patient selection and monitoring during the PMBV procedure⁽¹⁴⁻¹⁶⁾. Our study results are consistent with those reported in other regional centers, which have similarly observed high procedural success rates and significant improvements in the mitral valve area. The uniformity of outcomes across different Wilkins score echelons indicates broad applicability of the procedure. However, our study also identified manageable complications, especially among patients with higher Wilkins scores, which is consistent with the experiences of other centers in the region⁽¹⁷⁻¹⁹⁾.

Our study reaffirms that PMBV is an effective and safe treatment for RMS, with results closely aligning with those of local studies by Yuce et al.⁽²⁰⁾, Korkmaz et al.⁽²¹⁾ and Yıldız⁽²²⁾. We observed significant improvements in MVA and a reduction in transmitral gradients, consistent with the findings of Yuce et al.⁽²⁰⁾, who reported increases in MVA and symptom relief. Similarly, Korkmaz et al.⁽²¹⁾ and Yıldız⁽²²⁾ also demonstrated effective gradient reduction and improved pulmonary pressures. Our study showed a low complication rate, which matches the findings of Yuce et al.⁽²⁰⁾, who noted only a small increase in severe mitral regurgitation. Korkmaz et al.⁽²¹⁾ and Yıldız⁽²²⁾ also reported low complication rates, emphasizing the importance of operator skill in ensuring safety. We observed sustained improvements in MVA and patient function with few re-interventions. This echoes the durability of the results reported by Yuce et al.⁽²⁰⁾ with similar long-term benefits noted in the studies by Korkmaz et al.⁽²¹⁾ and Yıldız⁽²²⁾.

The minimal systemic impact of PMBV, as indicated by stable laboratory values, echoes findings from other studies that emphasize the safety of PMBV. However, the occurrence of complications in patients with higher Wilkins scores highlights the need for further research to refine the PMBV technique. Future studies should explore alternative approaches, such as balloon size adjustments or targeted interventions for specific mitral valve morphologies, to reduce the risk of complications⁽²³⁻²⁵⁾. The results of our investigations indicate the safety and efficiency of PMBV as a treatment option for patients with RMS. PMBV improved the MVA in various categories of patients, corresponding to different levels of disease severity according to their Wilkins score, with a success rate of up to 87%.

Study Limitations

While our study provides valuable insights, it is important to note its limitations, particularly its retrospective observational design, which may have introduced selection bias. Additionally, the concentration of this research in a single facility may limit the generalizability of the findings to other populations. Future multicenter, prospective studies are needed to validate these findings and ensure their broad applicability⁽²⁶⁻²⁹⁾. Consistency of our findings with those of these local studies highlights the reliability of PMBV. Despite some variations, the high success rates and safety profiles underscore the procedure's value as a standard treatment for RMS.

Conclusion

The study was specifically conducted to mitigate this condition by opening up the heart valves of 52 people who had contracted rheumatic fever and were diagnosed with severe MS. The study reported a procedural success rate of 87% in patients with RMS, showing significant improvements in mitral valve areas and gradients post-procedure. PMBV was also effective in patients with high Wilkins scores, leading to hemodynamic and symptomatic recovery. However, complications, such

as chordal rupture and MR progression, were observed in patients with higher Wilkins scores. Although these complications were manageable, the overall safety and efficacy of PMBV were underscored. The research results advocate for the use of PMBV as an appropriate alternative to surgery because PMBV is practical, low-risk, cost-effective, and efficient for improving hemodynamic and symptomatic outcomes among post-procedure patients with RMS.

Ethics

Ethics Committee Approval: Ethics Committee approval was obtained from the Van Yüzüncü Yıl Non-Interventional Clinical Research Ethics Committee (approval no.: 2019/10/11 date: 24.05.2019).

Informed Consent: Informed consent was obtained from all participants, ensuring their voluntary participation and confidentiality.

Authorship Contributions

Surgical and Medical Practices: Tüner H, Kaya Y, Concept: Tuncer M, Design: Tüner H, Kaya Y, Data Collection and/or Processing: Tüner H, Analysis and/or Interpretation: Tüner H, Tuncer M, Literature Search: Tüner H, Tuncer M, Writing: Tüner H.

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