Acute and long-term follow-up results of percutaneous mitral balloon valvuloplasty: a single-center study

Perkütan mitral balon valvüloplastinin akut ve uzun dönem takip sonuçları: Tek merkez çalışması

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Abstract

Objective: Percutaneous mitral balloon valvuloplasty (PMBV) is the method of choice in treatment of patients with hemodynamically significant mitral stenosis. We aimed to analyze acute and long-term clinical and echocardiographic consequences of PMBV.

Methods: In this retrospective cohort study; 311 patients who underwent PMBV in our Cardiology Clinic at Türkiye Yüksek İhtisas Education and Research Hospital between January 2000 and March 2004 were evaluated for acute procedural outcomes and primary endpoints (death, rePMBV, mitral valve replacement (MVR)). All 311 patients were contacted by phone call or letter at least five years after the procedure. Of the 311 patients, 87 who defined NYHA class II-IV symptoms were invited for a control visit and detailed echocardiographic evaluation. Sixty-three patients out of 87 who completed follow-up were enrolled for long-term consequences. Those 63 patients were subclassified into two groups as those without any negative event (n=26) (Group 1) and those with mitral valve area (MVA) (<1.5 cm²), rePMBV or referral to MVR (n=37) (Group 2) on follow up to 6.4±1.6 years.

Results: In the analysis of 311 patients, acute post procedural success, which was defined as mitral valve area (MVA) \geq 1.5 cm² without severe mitral regurgitation, was 94% and was only associated with preprocedural MVA (p=0.008). In the logistic regression analysis, preprocedural MVA was the only independent parameter, associated with acute procedural success (Expβ=0.004, 95%CI 0.0001-0.234, p=0.008). In the long-term follow up of 63 patients, the patients with uneventful course (Group 1) had significantly higher MVA (p<0.001), lower mean (p=0.001) and peak (p<0.001) transmitral gradients immediately after the procedure when we compared to the patients in Group 2. It was also noticed that patients with at least 60% improvement in MVA experienced composite end point much less frequently compared to those with less than 60% improvement in MVA (p=0.009). Kaplan-Meier analysis yielded significantly diverging cumulative survival curves for those with and without at least 60% improvement in MVA (p=0.003).

Conclusion: Concerning long-term follow up data of patients undergoing PMBV in a single center, it seems only acute postprocedural MVA was significantly associated with long-term consequences. (Anadolu Kardiyol Derg 2011; 11: 515-20)

Key words: Mitral valve stenosis, echocardiography, balloon valvuloplasty, logistic regression analysis, survival

ÖZET

Amaç: Perkütan mitral balon valvüloplasti (PMBV) hemodinamik olarak, ciddi mitral darlıklı hastaların tedavisinde tercih edilen yöntemdir. Biz PMBV'nin akut ve uzun dönem klinik ve ekokardiyografik sonuçlarını analiz etmeyi amaçladık.

Yöntemler: Bu retrospektif kohort çalışmada Ocak 2000-Mart 2004 tarihleri arasında Türkiye Yüksek İhtisas Hastanesi, Kardiyoloji Kliniğinde, PMBV uygulanan 311 hasta, akut sonuçlar ve primer son noktalar [ölüm, yeniden PMBV, mitral kapak replasmanı (MKR)] yönünden değerlendirildi. Bu 311 hastanın tümüne işlemden en az 5 yıl sonra olmak üzere telefon ya da mektupla ulaşıldı. New York Heart Association (NYHA) sınıf 2-4 semptom tarifleyen 87 hasta kontrol vizite ve detaylı ekokardiyografik inceleme için davet edildi. Takibe gelen 87 hastanın 63'ünde uzun dönem sonuçlar değerlendirildi. Altmış üç hasta ortalama 6.4±1.6 yıllık takipte olaysız olanlar (26 hasta) (Grup 1) ve mitral kapak alanı (MKA) <1.5 cm², yeniden PMBV, MKR kararı alınanlar (37 hasta) (Grup 2) olmak üzere 2 gruba ayrıldı.

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Bulgular: Çalışmadaki 311 hastanın analizinde ciddi mitral yetersizliği olmadan mitral kapak alanı (MKA) ≥1.5 cm² olarak tanımlanan akut işlem başarısı %94 idi ve yalnızca işlem öncesi MKA ile ilişkiliydi (p=0.008). Lojistik regresyon analizinde, işlem öncesi MKA akut işlem başarısı ile ilişkili olan tek bağımsız parametreydi (Ekspβ=0.004, %95 GA 0.0001-0.234, p=0.008). Uzun dönem takibe ait 63 hastanın olaysız hasta grubu (Grup 1), Grup 2'deki hastalara göre işlemden hemen sonra daha büyük MKA (p<0.001), daha düşük ortalama (p=0.001) ve pik (<0.001) transmitral gradiyente sahipti. Aynı zamanda MKA'da en az %60 düzelme olan hastaların olmayanlara göre birleşik son noktaya daha az ulaştıkları görüldü. Kaplan-Meier analizi ile MKA'da %60 düzelme olan ve olmayanlar arasında anlamlı birbirinden ayrışan kümülatif sağkalım eğrileri elde edildi (p=0.003).

Sonuç: Tek merkezde PMBV uygulanan hastaların uzun dönem verileri dikkate alındığında yalnızca işlem sonrası akut MKA'nın uzun dönem sonuçlarla ilişkili olduğu görülmüştür. (Anadolu Kardiyol Derg 2011; 11: 515-20)

Anahtar kelimeler: Mitral darlık, ekokardiyografi, balon valvüloplasti, lojistik regresyon analizi, sağkalım

Introduction

Percutaneous mitral balloon valvuloplasty (PMBV) has been developed as an alternative modality to surgical closed commissurotomy for mitral stenosis (MS) (1), and excellent hemodynamic improvement with favorable outcome has been reported by many investigators (2-11). Although numerous studies have documented favorable immediate and intermediate-term results, long-term echocardiographic follow-up studies are rare (1-6, 10-13).

In addition, cumulative clinical experience shows that restenosis and late functional deterioration developing 5 years after PMBV can be potentially important clinical dilemma, especially when discussing indications for PMBV (9). Restenosis rate after PMBV has been reported to range from 3% to 70% at 1-3 years (10-12).

The purpose of this study was to determine the acute and longterm clinical and echocardiographic results of consecutive patients who underwent PMBV at a single institution. These data were analyzed to identify factors influencing the long-term outcome.

Methods

Study design and population

In this single-center study, we retrospectively evaluated consecutive 311 patients (66 male and 245 female with a mean age of 36.2±9.7 years) who underwent PMBV in our Cardiology Clinic, Türkiye Yüksek İhtisas Education and Research Hospital for symptomatic moderate or severe MS between January 2000 and March 2004. A follow-up program beyond five years was scheduled. We contacted 311 patients either by phone or letter at least 5 years after the procedure. These patients were questioned about the functional status and for the primary endpoints (death, rePMBV, mitral valve replacement (MVR). Eighty-seven of 311 patients who defined New York Heart Association (NYHA) class II-IV symptoms were invited for a control visit and detailed echocardiographic evaluation.

After getting local Ethics Committee approval, a written informed consent was obtained from all patients, who accepted to participate. Sixty-three of 87 patients with NYHA class II-IV symptoms accepted to attend control visit and were evaluated by detailed echocardiographic examination for long-term consequences.

Those 63 patients were subclassified into two groups as those with uneventful (n=26) and those with re-narrowing of the mitral valve area (MVA) (<1.5 cm²), rePMBV or referral to MVR (n=37) on follow up to 6.4 ± 1.6 years.

Baseline clinical and follow-up variables

We noted the subjects' clinical and demographic characteristics, which included age, sex, body mass index, history of arterial hypertension (systolic blood pressure \geq 140 mmHg or diastolic blood pressure \geq 90 mmHg), diabetes mellitus, NYHA functional status, medications, the period of time after PMBV procedure and interventions during the period after PMBV.

The 12-lead ECGs were obtained at the standard article speed of 25 mm/s and calibration of 10 mm/mV from all of the patients and cardiac rhythms were recorded.

Echocardiographic and Doppler examinations

Two-dimensional and Doppler echocardiographic studies were performed before and after the procedure in all patients and in 67 patients at control visit by using a Vivid 7 Pro cardiac ultrasound system (General Electric, Horten, Norway) with appropriate probe. In addition to transmitral gradient (MG) and the peak transmitral gradient (PG), mitral valve area (MVA) was calculated from the Doppler study (using the pressure half-time method) and also by planimetry of the mitral valve orifice in parasternal short-axis view. Systolic pulmonary arterial pressure (SPAP) was estimated by continuous wave Doppler interrogation of the tricuspid regurgitant jet, using the modified Bernoulli equation.

Morphological features of the mitral valve were semi-quantified according to mitral Wilkins score (MWS), which was obtained by adding the scores of each of the following individual morphologic features: leaflet mobility, thickness, calcification, and subvalvular lesions (14). Mitral and tricuspid regurgitation (TR) were graded from 0 to 4+, depending on the spatial extent of the color flow jet area expressed as a percentage of left and right atrial area. Each patient served as their own control.

Percutaneous mitral balloon valvuloplasty

Indications for PMBV were as follows: symptomatic patients with moderate or severe mitral stenosis (MS) with favorable valve morphology (MWS \leq 8); asymptomatic patients with moderate to severe MS and pulmonary hypertension (SPAP \geq 50 mm Hg at rest or \geq 60 mm Hg with exercise) with favorable valve morphology; and symptomatic patients with moderate or severe MS with unfavorable valve morphology but not considered candidates for surgery or at high risk for surgery. Mitral valve area <1.5cm² and the mean transmitral gradient (MG) >5mmHg was defined as moderate or severe MS.

All patients underwent PMBV using the stepwise Inoue balloon technique as described previously (1). All transseptal punctures were performed by an experienced operator. Standard hemodynamic measurements of right and left heart pressures were performed; simultaneous measurements of left atrial and left ventricular pressures were also done. Mean mitral gradient and MVA were calculated using the Gorlin formula; cardiac output was determined by Fick or thermodilution method. All hemodynamic measurements were obtained before and immediately after PMBV.

The PMBV was considered successful if the MVA was >1.5 cm² without grade 3-4 MR in Doppler study.

Long-term follow-up

Sixty-three patients were followed up for 6.4 ± 1.6 years. Event-free survival was defined as no death, MVR, rePMBV or NYHA class III or IV symptoms. Restenosis was defined as >50% loss of the original increase in MVA, with follow-up MVA <1.5 cm². Clinical evaluation was accomplished by direct interview at clinic rounds. At the follow-up visit, exercise capacity was evaluated according to NYHA functional classification and echocardiography, including the assessment of MVA and pressure gradient was performed.

Statistical analysis

Statistical analysis was performed using SPSS software (14.0 for Windows; SPSS Inc, Chicago, III, USA). Parametric variables are expressed as mean±standard deviation, and categorical variables are expressed as percent. Independent parametric variables were compared via independent sample's t-test, and categorical data with Chi-square test. Temporal change of parametric variables were studied via paired samples' t-test. All patients regardless of successful PMBV were included in the analysis. Parameters that achieved a significance level of p less than 0.20 were incorporated in a multivariate logistic regression model.

Kaplan-Meier estimates were used to determine event-free survival in the group of patients who gave informed consent for follow up (freedom from death, MVR, or redo PMBV). Comparison between groups was performed using the log rank test.

Results

Baseline characteristics and immediate outcomes

The study involved a total of 311 patients, comprising 63 long term clinical and echocardiographic follow-up patients. All 311 patients were divided into two groups due to acute postprocedural results as successful PMBV (MVA 1.5 cm² or greater with post-PMBV MR grade <3) (Group 1) and unsuccessful PMBV (Group 2). All patients underwent successful septostomy and mitral valves were passed by balloon. Acute success was obtained in 293 patients (94%). Eighteen inadequate immediate results were related to suboptimal valve opening (valve area < 1.5 cm²) in 13 cases (4.18%) and severe MR (grade \geq 3) in 5 cases (1.6%). These 18 patients with suboptimal results were not included into further long-term analysis. Preprocedural clinical, echocardiographic and hemodynamic characteristics of two groups are shown in Table 1. Preprocedural rhythm was atrial fibrillation (AF) in 47 patients. At the end of procedure, 4 patients turned into sinus rhythm, whereas, new onset AF was observed in 8 patients.

Baseline clinical, echocardiographic and hemodynamic parameters were similar between groups except for preprocedural MVA which was significantly lower in unsuccessful group (p=0.008). Scores of subvalvular thickening (p=0.656), leaflet mobility (p=0.212), leaflet thickening (p=0.333), leaflet calcification (p=0.617) were also similar between groups.

Predictors of acute procedural PMBV success

In the 311 procedures, preprocedural variables were evaluated by univariate analysis as predictors of PMBV success. Complete information was available in all procedures. Only preprocedural MVA was statistically significant predictor of acute procedural success in the univariate analysis (Table 1). In the logistic regression analysis, preprocedural MVA (enrolled into analysis as a continuous variable) was the only independent parameter, associated with acute procedural success (Exp β =0.004, 95%CI 0.0001-0.234, p=0.008).

Table 1. Preprocedural clinical, echocardiographic and hemodynamic
characteristics of all patients (n=311)

Variables	Successful PMBV (n=293)	Unsuccessful PMBV (n=18)	*р
Age, years	36±9	34±7	0.312
Gender, F/M	232/61	13/5	0.611
Height, cm	156±12	154±13	0.912
Weight, kg	63±12	60±13	0.304
Glucose, mg/dl	93±15	93±16	0.976
Creatinine, mg/dl	1.0±0.5	0.9±0.4	0.843
Hemoglobin, g/dl	13.0±1.7	12.0±2.8	0.873
AF, n (%)	44 (15)	3 (16.7)	0.989
MVA, cm ²	1.10±0.14	1.00±0.14	0.008
MG, mmHg	11.3±3.0	11.5±2.7	0.638
PG, mmHg	20.3±5.3	21.3±4.9	0.398
SPAP, mmHg	51±15	51±14	0.936
LA diameter, cm	4.6±0.4	4.7±0.4	0.596
MWS	7.49±1.15	7.55±0.92	0.818
MWS >8, %	12	11	0.732
Grade 2 MR, n (%)	19 (6.5)	2 (11.1)	0.371
Moderate-severe TR, n (%)	126 (43)	9 (50)	0.632
**MG, mmHg	15±5	14±6	0.354

Data are expressed as mean±standard deviation and number/percentage

*independent sample's t-test and Chi-square test

AF - atrial fibrillation, F - female, LA - left atrium, M - male, MG - mean transmitral gradient, MR - mitral regurgitation, MVA - mitral valve area, MWS - mitral Wilkins score, SPAP - systolic pulmonary artery pressure, TR - tricuspid regurgitation **measured from catheterization Echocardiographic MG, PG, SPAP and MG in catheterization decreased significantly after valvuloplasty, with a corresponding increase in MVA measured at echocardiography and cardiac catheterization (Table 2).

There were no deaths, pericardial tamponade and cerebrovascular accident (CVA) in postprocedural hospitalization period. Access site complications were noticed in 4 patients (1.28%) as localized hematoma. There was no venous thrombosis in any of the patients. Postprocedural severe MR (grade \geq 3) was detected in 5 patients. Two of 5 underwent operation at long term follow-up.

Long-term outcomes

Two deaths occurred at follow-up, one died after a large cerebral infarction following cerebral embolism in the setting of AF 6 months later the procedure and one died following end stage renal failure deemed unrelated to his cardiac condition 14 months later the procedure. Fourteen out of 293 patients who developed NYHA III-IV symptoms underwent reintervention for severe symptomatic restenosis (redo PMBV in 6 patients and MVR in 8 patients). Six patients were in NYHA functional class III-IV and still awaiting reintervention.

In the long term follow up of 63 patients, baseline clinical and biochemical parameters were similar between groups (Table 3).

Baseline echocardiographic characteristics of the groups were similar between groups except for PG which was significantly lower in Group 1 (p=0.009) and percent improvement in MVA after PMBV in acute phase which was significantly lower in group 2 (56% vs. 80%, p<0.001). Patients with uneventful course (Group 1) had significantly higher MVA (p<0.001) and lower mean (p=0.001) and peak transmitral gradients (p<0.001) immediately after the procedure when we compared to the patients in Group 2.

When patients, who underwent echocardiographic examination for long- term follow- up, were classified according to presence or absence of at least 60% improvement in MVA after the procedure, there was a significant difference in between the two groups with reference to composite event, defined as renarrowing of the valve, reintervention to valve either with surgery or rePMBV. Overall, 42.5% of those with at least 60% improvement

 Table 2. Hemodynamic findings in 311 patients who had successful mitral valvuloplasty

Variables	Baseline Post-procedure		*р
MVA, cm ²	1.05±0.14	1.8±0.2	0.0001
MG, mmHg	11±3	4±2	0.0001
PG, mmHg	20±5	9±3	0.0001
SPAP, mmHg	51±15	37±11	0.0461
**MG, mmHg	15±5	4±4	0.009

Data are expressed as mean±standard deviation and number/ percentage

*independent sample's t-test and Chi-square test

MG - mean transmitral gradient, MVA - planimetric mitral valve area, PG - peak transmitral gradient, SPAP - systolic pulmonary artery pressure **measured from catheterization

Table 3.	Clinical,	biochemical	and	echocardiographic	parameters of
long-ter	m follow-	up groups			

Variables	Group 1 (n=26)	Group 2 (n=37)	*р
Age at the procedure, years	35.8	35.5	0.255
Gender, M/F, n	6/20	7/30	0.932
BMI, kg/m ²	24.3	25.3	0.297
Heart rate, beats/min	79	79	0.999
Atrial fibrillation	3/26	5/37	1.00
Hypertension	1/26	2/37	1.00
Smoking	5/26	6/37	0.750
NYHA class	2.4	2.5	0.229
Glucose, mg/dl	90	91	0.742
Urea, mg/dl	35	35	0.382
Creatinine, mg/dl	0.9	0.87	0.716
Hemoglobin, g/dl	14	13	0.647
Estimated GFR, ml/min	101.5	99.2	0.714
Preprocedural EF, %	68±4	67±5	0.303
Preprocedural MVA, cm ²	1.10±0.13	1.10±0.14	0.766
Preprocedural MG, mmHg	10.6±3.2	11.5±2.6	0.199
Preprocedural PG, mmHg	18.5±3.2	21.2±4.7	0.009
Preprocedural MPAP, mmHg	31.8±9	35.7±11.6	0.154
Preprocedural SPAP, mmHg	48.1±11.6	54.2±14.1	0.072
Preprocedural MWS	7.3±1.2	7.5±1.3	0.629
Acute percent improvement in MVA, %	80±24	56±24	<0.001
Severe calcification, n	11	10	0.320
Postprocedural MVA, cm ²	2.0±0.2	1.7±0.2	<0.001
Postprocedural MG, mmHg	4.0±1.0	5.2±1.5	0.001
Postprocedural PG, mmHg	8.6±2	11.3±2.8	<0.001
Postprocedural MPAP, mmHg	23.2±8.7	24.5±7.3	0.509
Postprocedural SPAP, mmHg	36.4±11.2	38.2±9.2	0.471
Postprocedural MVA after follow-up, cm ²	1.8±1.4	1.4±1.8	<0.001
Postprocedural MG after follow-up, mmHg	4.4±1	6.7±2.3	<0.001
Postprocedural PG after follow-up, mmHg	9.0±2.5	14.4±3.7	<0.001
Postprocedural MPAP after follow-up	14.7±5.5	20.1±6.8	0.001
Postprocedural SPAP after follow-up, mmHg	31.1±4.5	39.4±9.7	<0.001
Long-term percent change in MVA after follow-up, %	61.6±22.8	31.2±20.7	<0.001

Data are expressed as mean±standard deviation and numbe

*independent sample's t-test and Chi-square test

BMI - body-mass index, EF - ejection fraction, GFR - glomerular filtration rate, M/F - male/ female, MG - mean transmitral gradient, MPAP - mean pulmonary artery pressure, MVA - mitral valve area, MWS - mitral Wilkins score, NYHA - New York Heart Association, PG - peak transmitral gradient, SPAP - systolic pulmonary artery pressure in MVA experienced composite event during follow-up, whereas, 87% of those with less than 60% improvement in MVA experienced composite end-point (p=0.001). When patients (n=63) were compared according to cumulative event free survival (including those without reMVR or rePMBV), it was noticed that patients with at least 60% improvement in MVA experienced composite end-point much less frequently compared to those with less than 60% improvement in MVA (5% vs. 30.4%, p=0.009).

Kaplan-Meier analysis yielded significantly diverging cumulative survival curves for those with and without at least 60% improvement in MVA (Fig. 1).

Discussion

Our results showed that, while preprocedural MVA was associated with immediate procedural success, percent improvement in MVA with the procedure might predict the restenosis of mitral valve in the long-term.

PMBV is the procedure of choice to treat rheumatic MS in the majority of patients with moderate or severe MS who are symptomatic or have pulmonary hypertension. Rifaie et al. (15) showed that PMBV achieves comparable results to closed surgical commissurotomy both in the short and long-term. Careful patient selection, however, is necessary to achieve a successful outcome.

Predictors of immediate procedural results have been analyzed in prior series and indicate that determinants of success are multifactorial (1-6, 10-13). Early risk scores were comprised of semi quantitative assessment of leaflet thickening, subvalvular change, leaflet mobility, and valve calcification, and thus initial procedural experience was limited to patients with pliable, noncalcified mitral valves (14). Although MWS correlates with



Figure 1. Kaplan-Meier analysis of patients with and without 60% improvement in mitral valve area on follow-up. Cumulative survival indicates event free survival including those without reMVR and rePMBV (p=0.003)

Cum. - cumulative, MVA - mitral valve area, reMVR - redo mitral valve replacement, rePMBV - redo percutaneous mitral balloon valvuloplasty

PMBV results, their utility when considered in isolation has been challenged (16). Percutaneous mitral balloon valvuloplasty is frequently performed on patients previously considered poor candidates by echocardiographic score with acceptable results at the present day (7, 17). Furthermore, Güray et al. (18) was shown that PMBV after closed mitral commissurotomy was an effective alternative treatment of MS.

In our study, although MWS of 38 of total 311 patients was >8, acute postprocedural success was nearly 95% and was significantly higher than those in previous studies (17, 19). However, a new scoring system which was suggested by Rifaie may be more reliable and correlates with outcome better than the standard scoring system (20).

As a difference from previous studies which were concluded that the predictive value of combined clinical, echocardiographic, and hemodynamic parameters (7, 12, 14, 21), we identified that only preprocedural MVA assessed by echocardiography is a significant predictor of immediate procedural results. Importantly, in the subgroup of patients with less favorable anatomy by echocardiographic score (score >8), who are often excluded from undergoing PMBV on this basis, we have shown that if PMBV performed by experienced operator, success of PMBV will be similar between patients regardless of MWS. This finding was consistent with a previous study of Ekinci et al. (22).

Inoue balloon catheter is characterized by its low complication rate in comparison to the reported results of double balloon technique (23). CVA, pericardial tamponade and procedure related death were not encountered in our study, that is significantly lower compared to previous reports, which range between 1% and 2% (2, 3). We recommend to perform transesophageal echocardiography for all patients before PMBV regardless of AF or with prior thromboembolic history and also when the mitral valve morphology was not adequately assessed by transthoracic echocardiography.

In our study, we established that preprocedural higher peak gradient, higher MVA, lower mean and peak transmitral gradient and higher percent improvement in MVA immediately after the procedure were associated with better long-term outcome. Furthermore, we demonstrated that mitral morphology and preprocedural MVA were not related with long-term event-free survival. According to our study findings; when at least 60% of improvement in MVA occurs with PMBV, restenosis rate in the long term will be lower than that of patients whose improvement in MVA is below 60%. In other studies, the increase in MVA also has been defined as a predictor of restenosis and 1.8 cm² has been reported as a cut off value for postprocedural MVA (24). Mitral valve anatomy assessed by echocardiography has been indicated as a significant predictor of immediate procedural success and long-term restenosis (19, 24). We did not find a relationship between MWS and both acute procedural results and long-term restenosis.

Differences in age, clinical characteristics, and valve morphology may also account for the worse long-term event-free survival in the above reports from the United States and Europe compared with our series; accordingly, the long-term results of our study population cannot be extrapolated to the older-patient populations reported in the literature.

Study limitations

One limitation of this study is that only 63 patients completed long-term echocardiographic follow-up, but as the demographic characteristics and immediate post-procedural findings were similar to those of the main study population, this should not affect overall study findings. However, the excellent long-term results of this study cannot be extrapolated to the older patient populations seen in Europe and the USA.

Conclusion

It was concluded that PMBV provides excellent long-term outcomes for up to five years in patients with MS and if the procedure performed by experienced operator and high volume center although unfavorable mitral valve morphology, acceptable hemodynamic and symptomatic relief are achievable.

Conflict of interest: None declared.

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