The efficiency and safety of balloon valvuloplasty in patients with mitral stenosis and a high echo score: mid- and short-term clinical and echocardiographic results

Mitral darlığı olan ve eko skoru yüksek hastalarda balon valvüloplastinin etkinlik ve güvenilirliği: Erken-orta dönem klinik ve ekokardiyografik sonuçlar

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Objectives: We aimed to evaluate the success and safety of percutaneous mitral balloon valvuloplasty (PMBV) and its mid-term clinical and echocardiographic results in patients with symptomatic mitral stenosis, including those having a high echo score (9 to 11).

Study design: This prospective study included 57 consecutive patients (9 men, 48 women; mean age 41±9 years) who underwent PMBV with the Inoue technique for symptomatic (NYHA class II-IV) mitral stenosis (valve area <1.5 cm^2). The patients were divided into two groups according to the echo scores of ≤8 (Group One, n=25) and >8 (Group Two, n=32). Clinical and echocardiographic evaluations were performed before and after 24-48 hours of PMBV and during the follow-up period, including restenosis and major cardiovascular events.

Results: Patients in Group Two had significantly higher rates of atrial fibrillation (53.1% vs. 16%; p=0.006) and functional capacity of NYHA class III-IV (90.7% vs. 56%; p=0.01). Procedural success rates were 96% (n=24) and 90.6% (n=29) in Group One and Two, respectively. Failure occurred in one patient (4%) in Group One, and in three patients (9.4%) in Group Two. One patient in Group One developed severe mitral stenosis resulting in valve replacement. In Group Two, two patients developed hemopericardium. After the procedure, there was a two-fold increase from 1.0±0.1 cm^2 to 2.0±0.2 cm2 in the mean valve area, being more prominent in Group One (Group One: from 1.1±0.1 cm2 to 2.1±0.1 cm2; Group Two: from 0.9±0.1 cm2 to 1.8±0.1 cm^2; p<0.001). In-hospital mortality or embolic events did not occur, nor did restenosis or major cardiovascular events during a mean follow-up of 21±13 months.

Conclusion: Our results show that PMBV can be performed successfully in patients having a low (≤8) or higher (9-11) echo score, with satisfactory hemodynamic and symptomatic improvements.

Key words: Balloon dilatation; echocardiography; hemodynamics; mitral valve stenosis/therapy.

Amaç: Bu çalışmada eko skoru yüksek olan (9-11) hastalarında dahil edildiği semptomatik mitral darlığında perkütan mitral balon valvüloplastinin (PMBV) başarısı ve güvenilirliği ile orta dönem klinik ve ekokardiyografik takip sonuçları değerlendirildi.

Çalışma planı: İleriye dönük çalışmaya semptomatik (NYHA sınıf II-IV) mitral darlığı (kapak alanı <1.5 cm2) nedeniyle Inoue tekniği ile PMBV yapılan ardışık 57 hasta (9 erkek, 48 kadın; ort. yaş 41±9) alındı. Hastalar eko skoru ≤8 (grup 1,25 hasta) ve >8 olanlar (grup 2, 32 hasta) olarak iki gruba ayrıldı. Tüm hastalar, işlem öncesinde, işlemden 24-48 saat sonra ve sonrasındaki takiplerde klinik ve ekokardiyografik olarak değerlendirildi. Sonuçlar yeniden darlık gelişmesi ve majör kardiyovasküler olaylar açısından değerlendirildi.

Bulgular: Atriyal fibrilasyon (%53.1 ve %16; p=0.006) ve fonksiyonel kapasitesi NYHA III-IV (%90.7 ve %56; p=0.01) olan hastaların oranı grup 2'de anlamlı derecede daha yüksekti. İşlem başarısı grup 1 ve grup 2'de sırasıyla %96 (n=24) ve %90.6 (n=29) bulundu (p>0.05). Grup 1'de bir hastada (%4), grup 2'de üç hastada (%9.4) işlem başarısız oldu. Grup 1'de bir hastada ciddi mitral yetersizliği gelişti ve kapak değişimi yapıldı. Grup 2'de iki hastada hemoperikardiyum gelişti. İşlem sonrası ölçülen kapak alanında işlem öncesine göre ortalama iki kat artış sağlandı (1.0±0.1 cm2 ve 2.0±0.2 cm2). Bu artış grup 1'de daha fazla idi (grup 1'de 1.1±0.1 cm2 ve 2.1±0.1 cm2; grup 2'de 0.9±0.1 cm2 ve 1.8±0.1 cm2; p<0.001). Hastaneiçi ölüm ve embolik olay görülmedi. İki hasta grubunun ortalama 21±13 aylık takibi sırasında majör kardiyovasküler olay ve yeniden darlık görülmedi.

Sonuç: Semptomatik mitral darlığında PMBV eko skoru ≤8 olanlar kadar eko skoru 9-11 olanlarda da başarı ile uygulanabilmekte ve işlem sonrası hemodinamik ve semptomatik düzelmeler sağlanabilmektedir.

Anahtar sözcükler: Balon genişletmesi; ekokardiyografi; hemodinami; mitral kapağı darlığı/tedavi.

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Rheumatic valve diseases are an important health problem in developing countries.[1] Percutaneous mitral balloon valvuloplasty (PMBV) is a procedure which has been revealed to be an alternative to open and closed commissurotomy in the management of symptomatic mitral stenosis, currently the most common valvular disease. Short and long term results obtained from management with PMBV in patients with appropriate symptomatic and mitral morphology demonstrated that this treatment modality is as effective as surgical procedures.[2]

PMBV is currently performed in most patients with symptomatic mitral stenosis who have suitable valve anatomy; however, indication for this procedure is controversial in patients with an unsuitable anatomy. It is important to take into consideration the predicting factors for the outcome of PMBV and the experience of centers specialized in PMBV and surgical interventions, when making decisions about the management of this group of patients.[3,4] Despite the presence of clinical studies on the middle and long term outcome of balloon valvuloplasty in patients with rheumatic mitral stenosis, echocardiographic follow-up studies are relatively rare. In this study we investigated the effect and mid-term outcome of balloon valvuloplasty in patients with mitral stenosis, also including patients with high echo scores, in respect of valve anatomy.

PATIENTS AND METHODS

A total of 57 consecutive patients (9 men, 48 women; mean age 41±9 years) who underwent PMBV were included this prospective 4-year. A written informed consent form was obtained from the symptomatic (NYHA class II-IV) patients who had a valve area of <1.5 cm2, following provision of a detailed verbal information about the study. Approval of the study was obtained from the Local Ethics Committee.

Patients with a valve area of >1.5 cm2, moderate-severe mitral regurgitation (3+, 4+), those with observed thrombus in their transesophageal echocardiography, patients with other severe valve pathology requiring intervention, and those with very high echo scores (>12) were not included in the study.

Electrocardiographic evaluation. 12-lead surface electrocardiographic (ECG) recordings were obtained from all patients at a velocity of 25 mm/sec and calibration of 10 mm/mV. Atrial fibrillation (AF) was determined by the absence of P waves, presence of rough and fine fibrillation waves and variation in the RR intervals.

Echocardiographic evaluation. M-mod and Doppler evaluation of all patients was performed two-dimensionally by the GE-Vivid 3 echocardiographic device. All measurements were repeated at least three times and the mean values obtained. Patients were divided into two groups according to the echo scores of ≤8 (n=25) and >8 (n=32).

Measurements and calculations. (i) Mitral valve morphology scores from 1-16 were provided according to Wilkins' anatomic classification.[5] (ii) The mitral valve area (MVA) was calculated according to the planimetric (MVA-plan) and pressure half life (PHL).[6] (iii) Pulsed and continuous Doppler flow samples were obtained paralleled with the flow determined by color Doppler, for the calculation of pressure gradients. (iv) Left atrial diameter was measured as the anteroposterior diameter in the parasternal long axis view. (v) The degree of mitral regurgitation was graded from 1+ to 4+ taking into consideration color flow Doppler and the area of the left atrium covered by the regurgitation jet.[7] (vi) The highest systolic pulmonary artery pressure was calculated by addition of the estimated right atrial pressure to the highest pressure gradient obtained from the tricuspid regurgitation jet velocity.

Transesophageal echocardiography. Transesophageal echocardiography was performed in patients who were to undergo balloon valvuloplasty before the procedure, in order to exclude left atrial thrombus and to evaluate mitral valve morphology and regurgitation.

Valvuloplasty procedure. The balloon valvuloplasty procedure was performed by the transseptal approach through the right femoral vein using the Inoue balloon. Mitral regurgitation was evaluated before and after the procedure on left ventriculography according to Sellers' classification.[9] Success of the procedure was defined as MVA of >1.5 cm2 determined echocardiographically after the procedure and/or pre-procedural 50% increase in the value and the development of 3+ or 4+ mitral regurgitation.

Follow-up. Clinical and echocardiographic evaluations were performed before the procedure, 24-48 hours after the procedure, by the 3-6th months and every year thereafter. Recurrent stenosis was defined as >50% loss of MVA calculated after the procedure and/or a valve area of z1.5 cm2. Major cardiovascular event was defined as death, repeat of balloon valvuloplasty and the need for mitral valve replacement during the follow-up period.

Statistical analysis. Statistical analyses were performed using the SPSS version 13.0 software program. Continuous variables were expressed as mean±standard deviation, whereas categorical variables were expressed as percentage. Cross-tabulations and Chi-square analyses were employed for the evaluation of categorical variables. The McNemar test was used for comparative categorical data. The student's t-test was used for continuous data comparison of the two groups. Comparison of the

Table 1. Demographic, clinical and echocardiographic characteristics of patients before the procedure

	Total (n=57)			Echo score ≤ 8 (n=25)			Echo score > 8 (n=32)			
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p*
Age			41±9			40±9			42±9	0.553
Gender										0.063
Male	9	15.8		1	4.0		8	25.0		
Female	48	84.2		24	96.0		24	75.0		
Atrial fibrillation	21	36.8		4	16.0		17	53.1		0.006
NYHA functional class										0.01
II	14	24.6		11	44.0		3	9.4		
III	39	68.4		13	52.0		26	81.3		
IV	4	7.0		1	4.0		3	9.4		
Pre-procedure MR										0.163
0	31	54.4		15	60.0		16	50.0		
1	16	28.1		4	16.0		12	37.5		
2	10	17.5		6	24.0		4	12.5		

NYHA: New York Heart Association; MR: Mitral regurgitation.

two groups before and after the procedure, and during follow-up was performed using variance analysis. A $p<0.05$ value was considered as statistically significant.

RESULTS

Clinical and demographic characteristics of the patients are shown in Table 1. The rate of AF was significantly higher in patients with an echo score of >8 (53.1% and 16%; p=0.006). The number of patients with functional capacity of NYHA III and IV was higher in the group with and echo score of >8 (Table 1).

Success and complications of the procedure. The procedure was successful in 24 patients (96%) of the group with an echo score of ≤8 and in 29 patients (90.6%) of the group with an echo score of >8. The procedure was found to be unsuccessful in a total of four patients; in one patient (4%) of the group with echo score of ≤8 and in three patients (9.4%) of the group wit echo score of >8 (p=0.623). Valve replacement was performed following the development of sever mitral regurgitation due to chordal tear in one patient who had an echo score of ≤8 after the procedure. On the other hand, cardiac tamponade due to myocardial rupture during the procedure developed in another patient with unsuccessful procedure. This patient underwent pericardiosynthesis at the catheter laboratory and was later referred for elective surgery following a problem-free intensive care follow-up. A clinically insignificant pericardial fluid accumulation was observed in a patient following his successful valvuloplasty procedure. The echo score was >8 in these two patients who developed hemopericardium. However, these complications associated with the procedure did not create any difference between the two groups. No in-hospital mortality and embolic events were reported.

Post-procedural early outcomes. Echocardiographic and hemodynamic outcomes before, after and during the mid-follow-up period in the 53 patients who underwent successful PMBV are summarized in Table 2. The MVA which was measured planimetrically by echocardiography 24-48 hours after patients successfully underwent valvuloplasty was found to be on average two-fold higher than the value obtained before the procedure (1.0±0.1 cm2 and 2.0±0.2 cm2). The MVA obtained after the procedure was found to be higher in patients with an echo score of ≤8 (2.1±0.1 cm2 and 1.8±0.1cm2; $p<0.001$). Evaluation of all patients in terms of echo scores demonstrated that the valve area obtained after the procedure decreased with every increase in the echo score (Table 3).

Clinical and echocardiographic follow-up. The 53 patients who recorded successful procedures were followed up for a mean of 21±13 months. The follow-up period in patients with an echo score of ≤8 was 19±12 months, whereas that of those with an echo score of >8 was 23±13 months. Of the 53 patients four could not be contacted after the first visit (3-6 months), while six of them could not be contacted after the first year. Three patients could not come for their visit after the first year due to geographical difficulties; clinical data of these patients were thus obtained by telephone. Comparison of pre-procedural values in both groups demonstrated a significant increase in the MVA, difference in mean mitral pressure, decrease in the pulmonary artery pressure and also a significant decrease in left atrial diameter ($p<0.001$; Table 2). There were five patients in the NYHA II class with an echo score of >8, during the long term follow-up period. However, this record was not statistically significant (p=0.56). There was no major cardiovascular event (death, repeat of balloon valvuloplasty and mitral valve replacement) and no recurrent mitral stenosis during the follow-up period.

DISCUSSION

PMBV is currently performed in most patients with symptomatic mitral stenosis who have suitable valve

Table 2. Echocardiographic and hemodynamic outcomes after the procedure and during the mid-follow-up period in patients who underwent successful PMBV

	Total (n=53)			Echo score ≤ 8 (n=24)			Echo score > 8 (n=29)			
	n	%	mean±SD	n	%	mean±SD	n	%	mean±SD	*p*
MVA-pressure half life (cm^2)										
Pre-procedural			1.0±0.1			1.0±0.1			0.9±0.1	<0.001
Post-procedural			2.0±0.2			2.1±0.1			1.8±0.1	<0.001
Follow-up						2.0±0.1			1.7±0.1	<0.001*
MVA-planimetric (cm^2)										
Pre-procedural			1.0±0.1			1.0±0.1			0.9±0.1	<0.001
Post-procedural			2.0±0.2			2.1±0.1			1.8±0.1	<0.001
Follow-up						2.0±0.1			1.8±0.1	<0.001*
Mean pressure difference (mmHg)										
Pre-procedural			12±4			10±3			13±4.9	0.02
Post-procedural			5±1			5±1			6±1.8	0.02
Follow-up						5±1			5±1	<0.001*
Pulmonary artery pressure (mmHg)										
Pre-procedural			46±12			42±11			51±11	0.007
Post-procedural			35±8			32±7			38±8	0.007
Follow-up						29±5			33±5	
Left atrial diameter (mm)										
Post-procedural						44±4			48±6	<0.001
Post-procedural						-			-	
Follow-up						42±4			45±6	<0.001
Post-procedural MR										0.08
0	20	37.7		12	50.0		8	27.6		
1	14	26.4		3	12.5		11	37.9		
2	9	17.0		9	37.5		10	34.5		

MVA: Mitral valve areas; MR: Mitral regurgitation; *For comparison of pre-post procedural with preprocedural-follow-up

anatomy; however, indication for this procedure is controversial in patients with an unsuitable anatomy. The Mitral valve morphology and echo score have been shown by some studies to be the most important predicting factors for the success of the procedure.[4,10] However, our study demonstrates that balloon valvuloplasty may also be successful and effective in patients with relatively high echo scores.

The success rate of our study was found to be 93%; the post-procedural MVA was approximately two-fold higher in the group with an echo score of ≤8. This was proportional to a mean mitral pressure difference of more than 100%, systolic pulmonary pressure of approximately 20%, and a decrease in the left atrial diameter of approximately 10%. In addition, there was a significant improvement in the functional capacity, which continued through out the long clinical and echocardiographic follow-up period. Early results of our study were consistent with other studies which reported that PMBV provided clinical and hemodynamic improvement in cases with rheumatic mitral stenosis.[11,13]

Table 3. Distribution of patients according to echo scores and differences in the mitral valve area after balloon valvuloplasty

		Mitral valve area-planimetric (cm^2)	
Echo score	Number	Pre-procedural	Post-procedural
6	5	1.1±0.1	2.1±0.1
7	10	1.2±0.1	2.1±0.1
8	9	1.0±0.1	2.1±0.2
9	12	0.9±0.1	1.9±0.1
10	11	0.9±0.1	1.9±0.1
11	6	0.9±0.1	1.7±0.1

The success of the procedure was found to be higher in the group with an echo score of ≤8, although this result was not significant (96% and 90.6%). The post-procedural increase in the valve area was found to be significantly higher in the group with an echo score of ≤8 (2.1±0.1 cm2 and 1.8±0.1 cm2). Evaluation of all patients in terms of echo scores demonstrated that the valve area obtained after the procedure decreased with every increase in the echo score. The rate of post-procedural complications was found to be 5.2% (one patient in the group with echo score of ≤8 and two patients in the group with an echo score of >8). Various studies have reported the presence of mild

subvalvular fusion in movable leaflets with no calcification and a more than 90% success of the procedure and a 3% lower rate of complications in patients with no commissure calcification.[3,4,14,15] Success rate of the procedure was reported to be low (75-80%) and the rate of complications higher in patients with an unsuitable valve morphology and an echo score of >8.[5,11-13] Palacios et al.[4] in their study on 879 patients who underwent PMBV, demonstrated a procedural success of 86.5% in the group with echo score of ≤8 and of 76.6% in the group with an echo score of >8, and also reported a higher complication rate in patients with an echo score of >8. Among patients with an echo score of >8, 4.3% in-hospital mortality, 1% hemopericardium, 5.7% mitral valve replacement, and 1.3% stroke cases were reported. However, in the said study, the mean age of patients with an echo score of >8 was reported to be 63±14, patients with an echo score of ≤12 (mean echo score 10.2±1.4) and those with pre-procedural third degree mitral regurgitation (1%) were also included in the study, whereas higher rates of pre-procedural balloon valvuloplasty or history of commissurotomy were also reported (30%). This study also reported a valve area of less than 1.5 cm2 in patients with an echo score of ≤12 and an increased incidence of adverse events associated with long term recurrent stenosis. On the other hand, the mean age in our study was relatively low, the mean echo score was lower (patients with an echo score of >12 were not included) and procedural success rate of our may have been high and the complication rate low since it included patients with no severe mitral regurgitation before the procedure.

The experience of the center also plays an important role in the success of the procedure. Tuzcu et al.[16] reported that complication rates associated with valvuloplasty decreased in relation of the experience of the experienced team. Sanchez et al.[17] also demonstrated that the success rate of recently performed valvuloplasty procedure was high and the complication rate low, with regards to early stage outcomes, due to increase in clinical experience. Valvuloplasty has been performed in our clinic for many years now; the high success rate especially in patients with high echo scores, and the low rate of complication associated with the procedure may have been due to our careful selection of candidates for PMBV and the presence of an experienced team.

Valve area loss was found to be 0.04 cm2 during the follow-up period of our study. Various studies involving different patient groups have demonstrated that the annual valve area loss following PMBV was in the range of 0.1 to 0.4 cm2.[2,18-22] Hernandez et al.[23] reported the development rate of >0.3 cm2 valve area loss of 12% in the third year, 22% in the fifth year and of 27% in the seventh year. Comparison of these studies demonstrated a lesser valve area loss in our study. This may have been due to observation in our study of an echocardiographic follow-up period of more than two years in only 49% of the patients. Most studies with a greater decrease in the valve area have a follow-up period of more than three years.

No recurrent stenosis or major cardiovascular event (death, need for repeat balloon valvuloplasty and mitral valve replacement) was observed during the mean 21 months follow-up period in patients who underwent successful valvuloplasty. The survival rate during the 5-7 follow-up period was reported by various studies to be 82-100%.[2,18,24-27] Patients who were enrolled in these studies were clinically an echocardiographically heterogeneous. On the other hand, the survival rate was observed to be lower in studies involving more elderly patients. Evaluation of all cardiovascular events in our study demonstrated no events during the follow-up period. Related studies reported a wide range of an event-free survival rate of 16-80%.[27-29] The event-free survival rate of studies including a younger patients group was shown to be better. Ben Farhat et al.[2] reported a seven-year event-free survival rate of 90%, whereas Zaki et al. reported a 91% five-year event-free survival rate. This rate is very low in studies involving elderly patients.[14,23] Absence of any major cardiovascular event during the mean 21-year follow-up period may be explained by the high clinical experience of our center, in addition to the younger patients, the smaller sample size and the shorter follow-up period of our study.

Limitations. Of the 53 patients followed up in our study four could not be contacted after the first visit (3-6 months), while six of the patients could no be contacted after the first year. Three patients could not come for their visit after the first year due to socioeconomic problems; however, clinical data of these patients were obtained by telephone. Statistical analyses were no performed for unsuccessful procedures and the predictive effects of these procedures were not evaluated due to the inadequate sample size of our study.

In conclusion, PMBV can be performed successfully in patients with an echo score of 9-11 as well as in those with a score of ≤8, and the post-procedural hemodynamic and symptomatic improvements can be provided. These hemodynamic and clinical improvements also continued during the mid-follow-up period, in addition to the high early stage success of the procedure. These results show that PMBV can safely be performed if the right candidates for the procedure are selected and if the procedure is performed in centers with a clinically experienced team.

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