Percutaneous mitral balloon valvuloplasty: clinical and echocardiographic factors associated with success in a Tertiary-Care Hospital in Mexico

Valvuloplastía mitral percutánea con balón: factores clínicos y ecocardiográficos asociados con el éxito en un hospital de tercer nivel en México

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ABSTRACT

Introduction: Prevalence of mitral stenosis of rheumatic etiology has diminished. However, in Mexico there are some regions where still represents a health issue in productive population. Percutaneous valvuloplasty has become the treatment of choice in those with favorable anatomy. When successful immediate results are obtained, adequate long-term results are predicted. **Objective:** To determine the clinical and echocardiographic factors associated with the immediate success of percutaneous mitral valvuloplasty. **Material and methods:** A comparative and retrospective cross-sectional, observational study. Clinical records of patients treated with percutaneous valvuloplasty between 2000-2016 were reviewed. We studied clinical, echocardiographic, and procedural factors associated with immediate success. Descriptive and inferential statistics were used with SPSS v2.4 package. **Results:** A total of 363 patients. Female gender 287 (79.1%), age 50.8 ± 10.9 years. Functional class II 218 (60.1%). Atrial fibrillation 201 (55.4%). Previous procedure 78 (21.5%). Wilkins score 8-10: 228 (62.8%). Previous moderate mitral insufficiency 20 (5.5%). Inoue Balloon used in 343 (94.5%). We achieved success in 309 (85.1%), 26 had complications (7.16%), one death. We observed an increased number of complications in patients with pulmonary hypertension (> 60 mmHg) (p = 0.01), transvalvular gradient (mean > 10 mmHg) (p = 0.049), previous moderate mitral regurgitation (p = 0.001), and procedures with double-balloon (p = 0.001). We identified as unfavorable predictors of the procedure with statistical significance: Wilkins score 8-10 points (OR 2.6, 95% CI, 1.3-5.2) and previous moderate mitral regurgitation (OR 3.3, 95% CI, 1.28-8.93). **Conclusion:** Similar results were obtained with previous studies (success, complications and mortality). Only the Wilkins score greater than 8 points and the previous moderate mitral regurgitation were unfavorable predictors for the success of the procedure.

RESUMEN

Introducción: La prevalencia de estenosis mitral de etiología reumática ha disminuido. Sin embargo, en México hay regiones donde aún representa un problema de salud en la población productiva. La valvuloplastia percutánea se ha convertido en el tratamiento de elección en pacientes con anatomía favorable. Cuando se obtienen resultados inmediatos exitosos, se predicen resultados adecuados a largo plazo. Objetivo: Determinar factores clínicos y ecocardiográficos asociados con el éxito inmediato de la valvuloplastia mitral percutánea. Material y métodos: Estudio observacional, transversal, comparativo y retrospectivo. Se revisaron las historias clínicas de los pacientes tratados con valvuloplastia percutánea entre 2000-2016. Estudiamos los factores clínicos, ecocardiográficos y de procedimiento asociados con el éxito inmediato. Se utilizaron estadísticas descriptivas e inferenciales con el paquete SPSS v2.4. Resultados: Un total de 363 pacientes. Género femenino 287 (79.1%), edad 50.8 ± 10.9 años. Clase funcional II 218 (60.1%). Fibrilación auricular 201 (55.4%). Procedimiento previo 78 (21.5%). Puntaje de Wilkins 8-10: 228 (62.8%). Insuficiencia mitral moderada previa 20 (5.5%). Se utilizó Balón Inoue en 343 (94.5%). Logramos éxito en 309 (85.1%), 26 tuvieron complicaciones (7.16%), una muerte. Observamos un mayor número de complicaciones en pacientes con hipertensión pulmonar (> 60 mmHg) (p = 0.01), gradiente transvalvular (media > 10 mmHg) (p = 0.049), regurgitación mitral previa moderada (p = 0.001) y procedimientos con doble globo (p = 0.001). Se identificaron como predictores desfavorables del procedimiento con significación estadística: puntuación de Wilkins 8-10 puntos (OR 2.6, IC 95%, 1.3-5.2) y regurgitación mitral moderada previa (OR 3.3, IC 95%, 1.28-8.93). Conclusión: Se obtuvieron resultados similares con estudios previos (éxito, complicaciones y mortalidad). Sólo el puntaje de Wilkins mayor de 8 puntos y la regurgitación mitral moderada previa fueron factores predictivos desfavorables para el éxito del procedimiento.

INTRODUCTION

From the end of the 19th century, rheumatic fever and its cardiac complications have been a great public health issue in the western world. Since the use of penicillin, the prevalence of mitral valve pathology of rheumatic etiology has diminished in Mexico, however there are some regions where the disease has not yet been eradicated, therefore this disease still represents a health issue in the productive population.[1]

Rheumatic fever is an autoimmune inflammatory process with multiorgan involvement. The valvular involvement due to the chronic inflammatory process leads to thickening of the valves, fibrosis, fusion and shortening of the valves and commissures, and finally deformation, reduction and calcification of the mitral annulus.[2]

Mitral stenosis is a late complication, usually after 10 to 20 years. It is more common in women. Valve regurgitation is more common in men.[3]

There are several options for treating symptomatic valvular stenosis: a) surgical closed mitral commissurotomy (CMC), b) surgical open mitral commissurotomy (OMC), c) percutaneous techniques and finally, d) valve replacement.[4]

Surgical options are associated with restenosis rates of less than 10% at ten years, however disadvantages are thoracotomy, extracorporeal circulation, and surgical morbidity with longer hospital stay and increased costs.[4,5]

In 1982 Kanji Inoue, Japanese cardiothoracic surgeon, designed the percutaneous mitral commissurotomy with a rubber balloon.[6] Since then, the percutaneous mitral valvuloplasty (PMV) has become the treatment of choice of mitral stenosis with suitable anatomy.[7,8]

The success rate for the PMV depends on multiple factors:[8-10]

- Clinical: age over 50 years, weight and height, comorbidities, functional status (based on New York Heart Association classification), atrial fibrillation and previous surgical or percutaneous commissurotomy.

- Anatomical and hemodynamic: narrow valve area, previous mitral regurgitation, tricuspid regurgitation, valvular calcification, trans-mitral gradient, pulmonary hypertension, echocardiography Wilkins score.

Therefore, echocardiography is important for adequate evaluation and selection of patients.

When immediate post-procedure results are successful, adequate long-term results are predicted. When initial results are suboptimal, it is expected that patient's symptoms will not improve or only improve transiently and is associated with the need for surgical treatment in short term.[11,12]

Our hospital, a tertiary referral center, has eighteen years of experience in PMV. Therefore, the aim of this study is to determine the clinical and echocardiographic related factors associated with success of PMV.

MATERIAL AND METHODS

This is a comparative, retrospective, cross-sectional and observational study. We evaluated clinical records of patients with diagnosis of rheumatic severe mitral stenosis who were treated with PMV from 2000 to 2016 in the High Speciality Medical Unit Num. 34 of Mexican Institute of Social Security, in Monterrey, Nuevo León, México. They should have complete medical records for analysis and fulfill the inclusion criteria: age over eighteen-years old, mitral valve area (MVA) $\leq$ 1.5 cm^2, symptoms (NYHA class > 2), echocardiographic Wilkins' score < 10 pts, mild to moderate subvalvular calcification, no severe mitral regurgitation. We excluded patients with severe mitral regurgitation, another pathology that warrants cardiac surgery and Wilkins' score > 10 p.

We defined success of PMV: achieved MVA > 1.5cm^2, post-procedure non-severe mitral regurgitation and a decrease in mean trans-mitral gradient to less than 10 mmHg.[10,13]

For the purpose of analysis, patients were divided in two groups according to achieved or not immediate success of PMV and then we analyzed the following variables to find the more prevalent in each group:

- Clinical variables: age over 50 years, heart rhythm, functional status (NYHA classification), previous stroke, previous surgical or percutaneous commissurotomy, thrombus in left atrial appendage.

- Echocardiographic variables: Wilkins score (WS), MVA, left ventricular ejection fraction, systolic pulmonary arterial pressure (SPAP), transmitral mean gradient (TMMG).

Also, we determined the incidence of complications and reported acute complications: death, severe mitral regurgitation, cardiac tamponade, arrhythmias, vascular access complications, contrast related complications and thrombosis.

Patients were followed for 30 days, using digital clinical records of the institution and we evaluated adverse cardiovascular events: death, cardiac tamponade, urgent mitral valve surgery, arrhythmias and stroke.

We compared the characteristics of both groups and its association with the complications to determine also risk factors of procedure.

Statistical analysis

Descriptive statistics are expressed for continuous variables with mean and standard deviation (SD), frequencies and percentages for categorical variables. Baseline characteristics in the two groups were compared with chi square (χ^2) test, Fisher exact test and Student's t for categorical and continuous variables respectively. All characteristics were tested to determine statistical significance ($p < 0.05$) that correlates with immediate success of procedure. The significant variables were tested with multiple stepwise logistic regression to determine independent predictor of immediate unsuccessful procedure and complications (Odds Ratio with Confidence Interval 95%). Kaplan-Meier was used to determine survival and event free survival. All analysis with the use statistical package SPSS v2.4 (IBM).

RESULTS

From November 2000 until June 2016, 363 patients were included

Population characteristics

In *Table 1* the main characteristics of the population are described. There were 287

Table 1: Baseline characteristics.		
	n or mean	% o standard deviation ±
Total	363	100
Sex		
Male	76	20.9
Female	287	79.1
Age (yr)	50.89	10.96
Rhythm		
Atrial fibrillation	201	55.4
Wilkin's score		
< 8	135	37.2
8 a 10	228	62.8
Functional status (NYHA)		
I	27	7.4
II	218	60.1
III	111	30.6
IV	7	1.9
Previous stroke	41	11.3
Left appendage thrombus	13	3.6
Previous procedure	78	21.5
Surgical	24	6.6
PMV	46	12.7
Both	8	2.2
Technique		
Inoue	343	94.5
Double-Balloon	20	5.5
Ballon size	27.1	1.75
Insufflations	1.74	0.9
Pre-mitral regurgitation		
Mild	237	65.3
Moderate	20	5.5
Severe	0	0
LVEF		
Low	10	2.8
SPAP (mmHg)	49.68	17.4
TMMG (mmHg)	14.76	5.43
MVA (cm^2)	0.99	0.55
Pregnant	3	0.82

NYHA = New York Heart Association, LVEF = Left ventricular ejection fraction, MVA = Mitral valve area, SPAP = Systolic pulmonary arterial pressure, TMMG = Trans-mitral mean gradient, PMV = Percutaneous mitral valvuloplasty.

(79.1%) female and 76 (20.9%) male with mean age of 50.8 ± 10.9 years. There were 3 pregnant. Patients in functional class II were 218 (60.1%). Considerable proportion of the patients had atrial fibrillation with 201 (55.4%) of the cases. There were 13 (3.6%) patients with echocardiographic evidence of thrombus in left appendage.

Patients with a history of previous mitral procedure were 21.5%, 24 patients (6.6%) had a previous surgical intervention, 17 with open commissurotomy and 7 close commissurotomy, and 46 patients (12.7%) had a previous mitral balloon valvuloplasty. Furthermore, 8 patients (2.2%) had history of both types of previous procedures.

The echocardiographic evaluation reported that most patients (62.8%) had a Wilkins score between 8 and 10 points, the rest had a Wilkins score of less than 8 points. Twenty patients (5.5%) had moderate mitral regurgitation.

The pre-procedural hemodynamic conditions were: pulmonary artery systolic pressure of 49.6 ± 17.4 mmHg, mitral mean transvalvular gradient was 14.76 ± 5.43 mmHg, mitral valve area determined by Doppler or planimetry was 0.99 ± 0.55 cm².

Procedure

PMV was performed with Inoue technique in 343 (94.5%) patients, and with Double-Balloon technique in 20 patients (5.5%). The average size of the balloon was 27.1 ± 1.75 mm of diameter. The mean number of dilatations was 1.7 ± 0.9.

According to the previously established definition of success, it was obtained in 309 of the patients (85.1%) and it was not successful in 54 patients (14.9%), with a median increment in valve area posterior to the procedure of 0.88 ± 0.34 cm², with an average final valve area of 1.88 ± 0.8 cm² *(Table 2)*.

Predictors of unsuccessful procedure

The analysis *(Table 3)* of the data to determine predictors of unsuccessful PMV showed no association between sex (p = 0.636) and age over 50 years (p = 0.110). Atrial fibrillation was discretely more prevalent in the unsuccessful group but without statistical significance (33 (61.1%)-168 (54.4%); p = 0.358).

History of a previous surgical procedure (3 (5.6%)-21 (6.8%); p = 0.735), previous mitral valvuloplasty (9 (16.7%)-37 (12%); p = 0.339), or both (1 (1.9%)-7 (2.3%); p = 0.849) was similar in both groups.

Hemodynamic characteristics showed a similar tendency in both groups, including valvular area less than 1 cm².

The characteristics that showed statistical significance for an unfavorable result were a Wilkins' score between 8-10 points (43 (79.6%)-185 (59.9%); p = 0.006), and the presence of pre-procedural moderate mitral insufficiency (7 (13%)-13 (4.2%); p = 0.009).

The analysis with logistic regression to determine independent predictor for unfavorable results with statistical significance showed only two variables: Wilkins' score of 8-10 with an estimated OR of 2.6 (IC 95% 1.30-5.2; p 0.006) and previous mitral insufficiency with an OR 3.3 (IC 95% 1.28-8.93; p = 0.009) *(Table 4)*.

Table 2: Post-PMV mitral valve area improvement.					
Pre-MVA (cm²)		Post-MV (cm²)		Increase cm²	
Mean	Standard deviation ±	Mean	Standard deviation ±	Mean	Standard deviation ±
0.99	0.55	1.88	0.8	0.88	0.34

MVA = Mitral valve area, PMV = Percutaneous mitral valvuloplasty.

Complications

The incidence of acute complications of the procedure is shown in *Table 5*. Twenty six (7.16%) patients had complications. One

patient died during the procedure (0.3%), one patient (0.27%) developed atrial fibrillation with high ventricular response requiring electrical cardioversion; two patients (0.55%) developed acute intracardiac thrombus during the procedure, one of them presented embolism to upper extremities and underwent vascular surgery. One patient (0.27%) had an allergic reaction to contrast medium manifested by cutaneous rash. Other 4 patients presented vascular complications (hematomas) at the site of vascular access, none of them required additional vascular procedure. Eleven patients developed severe mitral insufficiency (3.03%), 5 of them required mitral surgery in the following 30 days (1.37%), the rest had mitral valve surgery in the next months. Three patients had pericardial effusion, but three other presented cardiac tamponade, and only one underwent surgical drainage.

We performed a univariate analysis and found that pulmonary arterial systolic pressure over 60 mmHg (p = 0.01), mean mitral transvalvular gradient over 10 mmHg (p = 0.049), previous moderate mitral insufficiency (p = 0.001) and double-Balloon techniques (p = 0.001) showed significant statistical association with complications *(Table 6)*.

Clinical follow-up

Clinical follow-up for 30 days post-procedure was possible in all patients, and its shown in *Table 7*. During the follow-up, three deaths occurred (0.82%), one during the procedure due to ventricular perforation, one patient developed ventricular fibrillation in the first 24 hours and the other died during vascular surgery to extract an embolus formed as a complication during valvuloplasty. Five patients went to surgery due to severe mitral regurgitation and valvular replacement was performed. Cardiac tamponade events (3) were previously described.

DISCUSSION

In this analysis that included 363 patients in which mitral balloon valvuloplasty was performed, we evaluated the main factors associated to success or failure of the procedure.

Table 3: Analysis of characteristics associated with successful percutaneous mitral valvuloplasty.					
	Unsuccessful PMV		Successful PMV		
	n	%	n	%	p
n	54	14.9	309	85.1	
Sex					0.636
Male	10	18.5	66	21.4	
Female	44	81.5	243	78.6	
Age					
> 50 years	23	42.6	168	54.4	0.11
Rhythm					
AF	33	61.1	168	54.4	0.358
Wilkin's score					0.006
< 8	11	20.4	124	40.1	
8 a 10	43	79.6	185	59.9	
Functional status (NYHA)					
> III	19	35.2	99	32	0.207
Previous stroke	5	9.3	36	11.7	0.609
Left appendage thrombus	1	1.9	12	3.9	0.459
Previous procedure	13	24.1	65	21	0.616
Surgical	3	5.6	21	6.8	0.735
PMV	9	16.7	37	12	0.339
Both	1	1.9	7	2.3	0.849
Insufflations					
> 2	11	20.4	81	26.2	0.362
Balloon					
Inoue	51	94.4	292	94.5	0.987
Double-Balloon	3	5.6	17	5.5	0.115
SPAP > 60 mmHg	19	35.2	78	25.2	0.128
TMMG > 10 mmHg	49	90.7	270	87.4	0.485
Pre-MR					
Moderate to severe	7	13	13	4.2	0.009
Low LVEF	2	3.7	8	2.6	0.644
MVA < 1 cm^2	41	75.9	217	70.2	0.394

NYHA = New York Heart Association, LVEF = Left ventricular ejection fraction, MR = Mitral regurgitation, MVA = Mitral valve area, SPAP = Systolic pulmonary arterial pressure, TMMG = Trans-mitral mean gradient, PMV = Percutaneous mitral valvuloplasty.

Analyzing the demographic characteristics of the patients, we found female gender to be the most prevalent, with almost 80% of the cases being women, and with a mean age around 50 years. In our study, 52% of the patients were older than 50 years, as found by Elisabete et al.[14]

The rest of the baseline characteristics in our population were similar to the information reported by previous studies,[7,14-16] except for the cardiac rhythm, in which atrial fibrillation was found to predominate in our center.[7,16]

The procedure was performed in three pregnant women, in which all were successful,

except one patient developed a left appendage thrombus and was treated with thrombolysis without any further complication. The procedure in the other two patients was safe and effective as reported previously by other centers.[17]

Regarding procedural characteristics, the most common balloon used was the Inoue balloon. Finding success rates of 85.1%, which are similar to those reported in other centers where success rates are between 85 and 90%.[10,18] We found an increase of almost 100% in mitral valve orifice.

According to the previous reports where certain characteristics, like history of previous procedure and very severe mitral stenosis (area less than 1 cm^2) represent technical difficulties and could alter success rates, however we found no significant association between those variables and failure.[3,9,19]

As previously reported and in our center, the PMV is safe and with high success rates, but we found only two factors associated to failure with statistical significance. Wilkins score between 8-10 points with odds ratio 2.6 (IC 95%; 1.3-5.2), and previous moderate mitral insufficiency with odds ratio 3.3 (IC 95%; 1.28-8.93). This is similar to the data reported in other centers. Moreover, in our center the number of patients with Wilkins score 8-10 points (63%) was greater than

Table 4: Predictors of unsuccessful percutaneous mitral valvuloplasty.

	Odds Ratio	IC (95%)	
Sex			
Male	0.83	0.40	1.70
Female	1.1	0.57	2.50
Age > 50 years	0.623	0.35	1.11
Atrial fibrillation	1.3	0.73	2.30
Wilkin's score > 8 p	2.6	1.30	5.20
Severe valvular calcification	1.41	0.77	2.56
Functional status (NYHA)			
III y IV	1.1	0.62	2.10
Previous stroke	0.77	0.29	2.06
Left appendage thrombus	0.467	0.05	3.66
Previous procedure	1.1	0.60	2.35
Surgical	0.807	2.32	2.80
PMV	1.47	0.67	3.25
Both	0.814	0.10	6.75
Insufflations			
> 2	0.72	0.35	1.46
Balloon			
Inoue	0.99	0.28	3.49
Double-Balloon	2.97	0.72	12.20
SPAP > 60 mmHg	1.6	0.89	2.97
TMMG > 10 mmHg	1.41	0.53	3.77
Pre-MR moderate to severe	3.3	1.28	8.93
Low LVEF	1.44	0.29	7.00
MVA < 1 cm^2	1.33	0.68	2.61

NYHA = New York Heart Association, SD = Standard deviation, LVEF = Left ventricular ejection fraction, MR = Mitral regurgitation, MR = Mitral regurgitation, MVA = Mitral valve area, SPAP = Systolic pulmonary arterial pressure, TMMG = Trans-mitral mean gradient.

Table 5: Acute complications.

	n	%
Dead	1	0.3
Severe MR	11	3.03
Pericardial effusion	3	0.82
Cardiac tamponade	3	0.82
Arrhythmia	1	0.27
Hematoma*	4	1.1
Contrast related**	1	0.27
Thrombus***	2	0.55
Total	26	7.16

MR = Mitral regurgitation.
* Femoral access, ** Allergic reaction, *** Intracardiac thrombus.

other series.[16,20] For example, the number of patients with these characteristics reported by Elisabete et al,[14] was only 8%. Selection of the patients with scores > 8 was made on the basis of low score on the subvalvular apparatus and the experience of the center. However, Wilkins score > 8 is associated to bad outcomes, in spite of acceptable success rate in our center, avoiding this condition could improve success rate. Echocardiographic evaluation of patients is essential, and consideration of clinical characteristics allows optimal selection of patients.[13]

Complications

Our complication rate was 7.16%, which is similar to those reported by other centers.[3,9,10] However, this percentage was due to minor complications, which do not have an impact on the patient's long-term outcomes (pericardial effusion, site access hematoma, arrhythmias, allergic reaction to contrast). In our registry, two patients developed intracardiac thrombus during the procedure (0.55%), a complication that is rarely reported

Table 6: Predictors of acute complications of percutaneous mitral valvuloplasty.

	Complication		No complication		
	n	%	n	%	p
n	26	7.2	337	92.8	
Sex					0.085
Male	2	7.7	74	22	
Female	24	92.3	263	78	
Age > 50 years	12	46.2	179	53.1	0.493
AF	13	50	188	55.8	0.567
Wilkin's score 8-10	9	34.6	126	37.4	0.778
Functional status (NYHA)					
III y IV	6	23.1	112	33.2	0.287
Previous stroke	2	7.7	39	11.6	0.547
Left appendage thrombus	0	0	13	3.9	0.308
Previous procedure	5	19.2	73	21.7	0.771
Surgical	2	7.7	22	6.5	0.818
PMV	3	11.5	43	12.8	0.857
Both	0	0	8	2.4	0.427
Insufflations	5	19.2	87	25.8	0.457
Balloon					
Inoue	24	92.3	319	94.7	0.613
Double-Balloon	2	7.7	18	5.3	0.001
SPAP > 60 mmHg	15	57.7	82	24.3	0.01
TMMG > 10 mmHg	26	100	293	86.9	0.049
Pre-MR					
Moderate to severe	5	19.2	15	4.5	0.001
Low LVEF	1	3.8	9	2.7	0.724
MVA < 1 cm^2	19	73.1	239	70.9	0.815

NYHA = New York Heart Association, SD = Standard deviation, LVEF = Left ventricular ejection fraction, MR = Mitral regurgitation, MR = Mitral regurgitation, MVA = Mitral valve area, SPAP = Systolic pulmonary arterial pressure, TMMG = Trans-mitral mean gradient, PMV = Percutaneous mitral valvuloplasty.
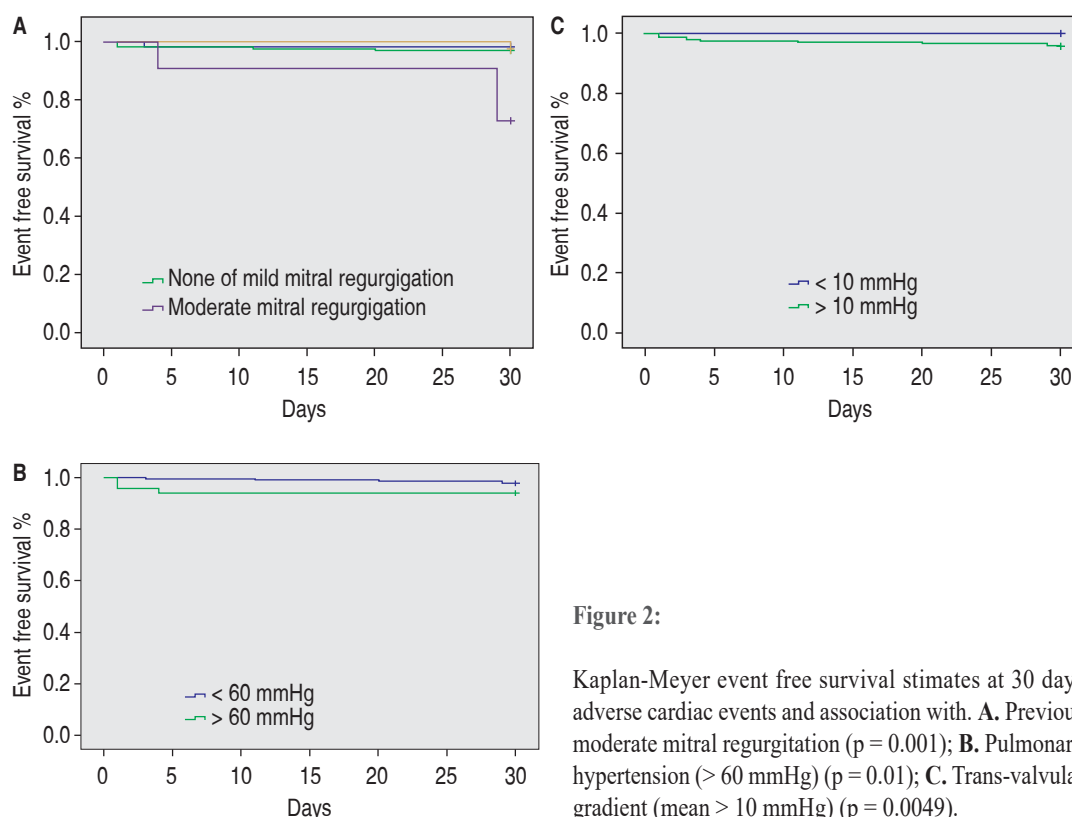
Table 7: Adverse events at 30 days.

	n	%
Death	3	0.82
Mitral surgery	5	1.37
Arrhythmia	1	0.20
Cardiac tamponade	3	0.82
Stroke	0	0.00
Total	12	3.30
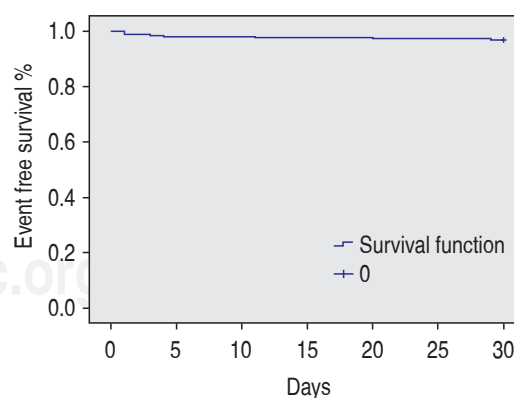
PMV = Percutaneous mitral valvuloplasty.

Figure 1: Adverse cardiovascular events post-PMV.

Figure 2:

Kaplan-Meyer event free survival stimates at 30 days adverse cardiac events and association with. **A.** Previous moderate mitral regurgitation (p = 0.001); **B.** Pulmonary hypertension (> 60 mmHg) (p = 0.01); **C.** Trans-valvular gradient (mean > 10 mmHg) (p = 0.0049).

in other series. Post-procedural severe mitral insufficiency was observed less than those reported by other centers.[21] We had an overall 30-day mortality of 0.82%, similar to other studies.[9,10,22]

In the follow-up the composite of death, mitral surgery, arrhythmia, tamponade and stroke was only 3.30%, which demonstrates the safety of the procedure.

We found characteristics associated with complications (pulmonary systolic arterial pressure > 60 mmHg, transmitral gradient > 10 mmHg, pre-procedural moderate mitral regurgitation, and the use of double-balloon technique), that forced us to be cautious in certain patients and techniques. Double-balloon techniques had already been associated with more complications.[6]

We assessed event-free survival at 30 days according to Kaplan-Meyer method, and elaborated survival curves *(Figure 1)*. Also, factors associated with adverse events were analyzed with survival curves *(Figure 2)*.

CONCLUSIONS

In our study, we had a successful procedure in 85.1% of the cases. The mortality and complications rates were similar to previous worldwide series.

We found that only Wilkins score ≥ 8 points and previous moderate mitral insufficiency are strong predictors of an unsuccessful valvuloplasty. We also found that a high number of patients in our study had a Wilkins score over 8 points, which could have diminished the number of successful procedures. Nevertheless, our success rate was within normal range.

In conclusion, all these variables should be taken into consideration in the selection process of the patients in order to choose the most accurate technique and improve the success rates while reducing complications.

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