IS REDO MITRAL BALLOON VALVULOPLASTY AS SAFE AND EFFICIENT AS A FIRST PROCEDURE ?

DORRA ABID, AHMED SIALA, LEILA ABID, FATENTRIKI, TARAK SALLEMI, MALEKAKROUT, MOURADHENTATI, SAMIR KAMMOUN.

Cardiology department, Hedi Chaker Hospital, 3029, Sfax, Tunisia

Summary

Introduction: Since its introduction in 1984, mitral balloon valvuloplasty became the treatment of choice for mitral stenosis. After a successful procedure, the major event on long follow up is restenosis which treatment is discussed between surgery or redo mitral balloon valvuloplasty (mbv).
Methods: Our study was a retrospective and descriptive one. In Hedichaker hospital between 1998 and 2008, 302 patients underwent ambv. Among these patients 35 required a new mitral balloon valvuloplasty during follow-up. In this study we report the immediate and long term results of this redo procedure and compare our results with the initial group of 302 patients who got a first mbv.
*Results:*Both groups were similar in terms of age (34 +/- 13 for de novo group versus 32 +/-11 for redo group) and female percentage 77 % vs 85 % (p=0,24). There was no difference between groups in term of pre procedural mitral valve area: (0.98 +/- 0.21 for the 302 patients and 1.01 +/- 0.20 for the 35 others), valve morphology quantified using the Wilkins score and pulmonary systolic pressures. The procedure was successful for 85 % of patients of the de novo group and only 77 % for the redo group (p =0.10).There was no exceed in major immediate complications such as hemopericardium, acute severe mitral regurgitation or death. During follow up eight cases or restenosis were noticed among the 35 patients group within a mean period of 20 months versus 41 cases in the other group. But the difference wasn't statistically significant.
Conclusion: Repeat mbv results in good immediate and long term outcomes with no exceed of complications especially in patients with favorable anatomic forms.

Key words: Mitral balloon valvuloplasty, restenosis, redux, mitral stenosis, rheumatic fever

INTRODUCTION

Mitral stenosis became less and less frequent due to the decrease of rheumatic fever incidence but it is still frequent in developing countries where rheumatic fever is endemic (1). Since its introduction in 1984 (2), mitral balloon valvuloplasty became the treatment of choice of mitral stenosis with high rates of success and few complications (3). After a successful procedure, the major event on long follow up is restenosis which is used to be treated with mitral valve replacement. Nowadays redo mitral balloon valvuloplasty seems to be a good solution for this issue. The aim of this study was to prove that redo mbv is as safe and efficient as a first procedure.

METHODS

Our study was descriptive and retrospective. In the cardiology department of HediChaker hospital, 302 patients underwent a mitral balloon valvuloplasty for the first time between 1998 and 2008 (group redo mbv). Among these patients, thirty five required a new valvuloplasty (group novo mbv). We compared these two groups in terms of epidemiologic, echographic, procedural characteristics and mbv results.

The demographic and clinical features were obtained through medical observations.

The echographic assessment of the mitral valve was performed with the transthoracic approach measuring mitral valve area using both methods: planimetryand the pressure half time by Doppler. Mean and maximum pressure gradients were measured. We searched for a concomitant mitral regurgitation, an aortic valve disease, a tricuspid regurgitation and calculated the level of systolic pulmonary pressure. The left atrium diameter and area were analyzed. We conclude the exam with the evaluation of the Wilkins score taking into account valve thickening and mobility, calcifications and sub valvular damage. The mitral valve was judged suitable for mbv if Wilkins score was less or equal than eight.

The trans esophageal approach was realized for all patients 24 hours before mitral balloon commissurotomy in order to exclude a left atriumthrombus considered as the main contraindication to mbv and to verify the regurgitation degree which is sometimes difficult to assess using only the trans thoracic approach.

All percutaneous mbv procedures were performed by the anterogradetransvenous approach using the Inoue balloon system.

The mitral valvuloplasty was judged successful if the mitral area became more than 1.5 cm2 without an increase of mitral regurgitation under second degree. The immediate result evaluation was assessed by hemodynamic measurements in cath lab and 24 hours later using echography. The aim of echography was to measure the mitral area, assess commissure split and search an increase of mitral regurgitation degree.

Long term follow up was achieved using medical observations and sometimes phone calls. Regular echographicexams wereperformed. Restenosis was defined as a mitral area becoming less than 1.5 cm2 after initially successful mbv.

Data were presented as mean ± SD. Comparison of hemodynamic variables was done using student t-test and chi-square test. Kaplan-Meier estimates were used to determine freedom fromrestenosis and event-free survival

RESULTS

Both groups were similar in terms of age, sex distribution, baseline mitral area, anatomic features, preexisting mitral regurgitation and level of pulmonary pressure. We noted a significant difference in atrial fibrillation at hospital admission: 26 % in group Novo mbv versus 8 % in group redo mbv. All these characteristics are summarized in table 1.

Table 1: baseline demographic and echgraphiccharacteristics

	Group novo mbv (302)	**Group redomvb (35)**	**p**
Age (years)	34.44 +/- 13	32.03 +/- 11	0.24
genderfemale	233 (77%)	30 (85%)	0.24
male	69 (23%)	5 (15%)	
Mitral area (cm2)	0.98 +/- 0.21	1.05 +/- 0.20	0.09
Wilkins <8	203 (67%)	22 (62%)	0.604
>8	99 (33%)	13 (38%)	
Mitral regurgitation	129 (42%)	9 (25%)	0.053
PAP (mmHg)	50.62 +/- 16.8	49.23 +/- 16.7	0.71
Atrial fibrillation	81 (26%)	3 (8%)	0.018

PAP : pulmonary artery pressure

Immediate results were evaluated directly in cath lab then with echography. We obtained a success rate of 87 % in group novo mbv versus 77% in group redo mbv but the difference wasn't significant. In the other hand we compared hemodynamic results and we noticed a better increase in mitral valve area for novo mbv group rising to 1.89 cm2 versus 1.74cm² for group redo mbv (p = 0.017) and a lower level of atria pressure 13.78 mmhg for group novo mbv 16.59mmhg for group redo mbv (p= 0.019) whereas pulmonary pressure decreased with similar rates.

We noticed a little number of immediate complications summarized in table 3. We found only two cases of acute severe mitral regurgitation representing 5.7 % of the redo mbv grouppopulation versus 19 cases in group novo mbv(5%). This difference wasn't statistically significant. This mitral regurgitation was already present and increased after procedure in one case and was new in the second. These two patients underwent a mitral valve replacement after 4 and six months. One procedure was complicated by tamponade needing urgent surgery with a good late evolution.

Table 2: Immediate echographic and hemodynamic results

	Group novo mbv (302)	Group redo mbv (35)	p
Success (%)	262 (87%)	26 (77%)	0.104
Post procedural mitral area (cm^2)	1.89 +/- 0.36	1.74 +/- 0.29	0.017
Post procedural atria pressure	13.78 +/- 6.47	16.59 +/- 5.59	0.019
PAP (mmHg)	35.43 +/- 12.8	33.38 +/- 7.6	0.38

Table 3: Mitral balloon valvuloplasty immediate complications.

Complications	Group novo mbv	Group redo mbv
Death	2(0.6%)	0
Embolism	2(0.6%)	0
Tamponade	1(0.3%)	1
Severe mitral regurgitation	17(5%)	2(5.7%)

Long follow up showed no differences between both groups. We noted no death in redo group in a mean follow up of 39.7 +/- 29 months. Eight patients developed restenosis in group redo mbvwith a delay of 20 months (22.8%) versus 41 patients of group novo mbv (13.57 %) in a delay of 53 months. Among these eight patients four got a third mitral balloon valvuloplasty with a good result, one patient underwent a mitral valve replacement, two patients were lost on follow up and one patient refused surgery.

Table 4: adverse events during long follow-up

Events on follow up	Group novo mbv	Group redo mbv
Restenosis	41 (13.57%)	8 (22.8%)
New valvuloplasty	35 (11.5 %)	4 (11.4%)
Valve replacement	24 (7.9%)	1 (2.85%)

DISCUSSION

Mitral balloon valvuloplasty is nowadays the treatment of choice for rheumatic mitral stenosis with high success rates related in all studies. It took the place of classic surgical commissurotomy. Restenosis is considered as the main cause of functional deterioration after a successful mbv (4). Restenosis rates range from 3 to 70 % with a one to three years delay (5) (6) (7). The most common mechanism is commissural refusion. In old studies, the mitral valve replacement (MVR) was considered as the only possible treatment for restenosis after surgical or percutaneous commissurotomy (8) because of the severity of the anatomic morphology. The problem is that surgical reintervention results in high operative risk and a lot of anti thrombotic therapy complications. The aim of our study was to prove that redo mbv was a good treatment for restenosis without major events. Few studies in literature reported results of repeat mitral balloon valvuloplasty after a successful initial procedure. Most of these studies included a small number of patients with a short follow up.

Our cohort included 35 patients with a mean age of 32 years and female were predominant with a sex ratio of 5.66. Our patients were younger than patients from occidental studies of Chmielak et al (9) or Pathan et al (10) and similar to Turkish Nuran et al (11) and Iranian Naser et al (12) studies.

Our population was characterized by a smaller number of patients with atrial fibrillation, more suitable valve anatomy attested with the Echo Wilkins score. Mitral valve area before procedure was at the same level than other authors.

Table 5: epidemiologic and echographic characteristics from litterature

	Our study	**Lung et al (13)**	**Chmielak et al (9)**	**Naser et al (12)**	**Pathan et al (10)**	**Nuran et al (11)**
Number	35	53	67	25	36	20
Gender (f) %	85%	89%	-	-	75%	95%
Age (years)	32	39	52	40	58	37
AF %	8%	11%	41%	32%	61%	-
Wilkins >8	38 %	-	7.5 +/- 1.3	9.56	50 %	85 %
MVA (cm^2)	1.05 +/- 0.22	1.03+/- 0.22	1.17 +/- 0.16	0.97	1.1	1.2 +/-0.2

MVA : mitral valve area; AF: Atrial fibrillation

Procedure success was defined as a mitral valve area becoming above 1.5 cm^2 without significant mitral regurgitation (14) (15). Our procedure was successful in 77 % of cases.Pathan et al (10) reported a success rate of 75 % but the population of his study was old (mean age 58 years) and most of them were in atrial fibrillation with an unfavorable valve anatomy. Lung et al (13) reported a higher success rate of 91 %. This rate is perhaps due to inclusion criteria. In fact Lung included young patients with commissural refusion and excluded patients with calcifications and comorbidities. Turkish study of Nuran et al (11) showed a success in 90 % of cases but this study included only 20 patients and excluded those in atrial fibrillation which is a condition known to have a poor prognosis value on immediate results (16). Fawzi et al (17)in their study between 1989 and 2003 included 56 patients. Procedure was done with a good result in 93 %. Fawzi et al demonstrated that suitable anatomic morphology was the strongest predictive factor of immediate results.

Severe mitral regurgitation represents the major complication of mitral balloon valvuloplasty and may lead to urgent surgery. Its frequency ranges from 1 to 10 % among studies about a first mitral valvulolasty (18) (19). Due to the small number of patients in studies concerning redo mbv, we noticed few complications. Severe MR occurred in 2 cases over 53 in Lung (13)study, 1 case over 67 in Chmielak cohort (9) and 2 cases in our population. We noted a single case of tamponade and no death. These results prove that repeated valvuloplasty is a safe technique.

Long term follow up showed 8 cases of restenosis (22.8 %) in a delay of 20 months and needing reintervention but no death occurred. Our follow up wasn't long enough after a redo mbv. Lung et al (13) reported a 74 % rate of survival without new intervention at 5 years. Chmielak et al (9) noted a rate of 77.3 % of survival with no need for mitral reintervention. Predictive factors of events like surgery or third mbv or heart failure in this last study were previous surgical commissurotomy and Wilkins score >7. Pathan et al (10) identified higher echographic scores, smaller post procedural mitral valve area and higher pulmonary pressure levels as factors of poor prognosis after redo mbv. These predictive factors are similar to those identified for first procedures (20) (21).Fawzi et al (17) reported a 40 % rate of restenosis on long follow up in his study over 56 patients. Turgeman et al (22) focused on the necessity to select the suitable patients for repeated mbv. The strongest predictive factor of success was the restenosis mechanism and the commissural refusion results in the best immediate and long term results. The valve anatomy includes also the subvalvular componentswhich interfere with the final results.

Repeated mitral balloon valvuloplasty is not the only treatment for restenosis following a first successful procedure. Many patients are referred to surgeons for usually a mitral valve replacement due to the valve anatomy judged unsuitable for a new mbv. In fact restenosis occurs more likely in older patients with high echographic scores. That's why most of the patients used to undergo surgery. Many studies compared results of redo mbv and surgery.

Kim et al (23) demonstrated that redo mitral balloon valvuloplasty is doing as good as surgery in the first four years. Then surgery results seemed to turn better due to the frequent necessity for reintervention in the group of patients treated with a new mbv.9 years survival free of adverse events

was 90 % in surgery group versus 36 % in redo group.Naser et al (12) reported high peri operative mortality for surgery (13.6 %) due to patients' selection. That why redo mbv is better in early follow up with lower rates of in hospital deaths. Mitral valvuloplasty costs also less than surgery in developing countries where rheumatic fever is still endemic and needs fewer days of hospitalization.

STUDY LIMITATIONS

It is a monocentric retrospective study with a small number of patients and a relatively short follow-up. This makes statistical analyses harder and less reliable.

CONCLUSION

Repeat mitral balloon valvuloplasty seems to be an efficient and a safe strategy for the treatment of restenosis after a first successful procedure. It is sure very important to include suitable patients with the optimal echographic characteristics and the commissural refusion as restenosis mechanism.

CONFLICT OF INTEREST

No conflict of interest to declare

ACKNOWLEGMENTS

We thank Doctor FaiçalElleuch who performed some of procedure for his friendliness and availability.

REFERENCES

1. McMurray JJ, Adamopoulos S, Anker SD, Auricchio A, Bo¨ hm M, Dickstein K et al.*ESC Guidelineslines for the diagnosis and treatment of acute and chronic heart failure 2012:The Task Force for the Diagnosis and Treatment of Acute and Chronic HeartFailure 2012 of the European Society of Cardiology. Developed in collaboration with the* . Heart Failure Association (HFA) of the ESC. Eur Heart J 2012;33:1787–1847.

2. Lock JE, Khalilullah M, Shrivastava S, et al. Percutaneous catheter commissurotomy in rheumatic mitralstenosis. N EnglJMed 1985 et 313:1515–8.

3. Cohen DJ, Kuntz RE, Gordon SPF, et al. Predictors of long-term outcome after percutaneous mitral valvuloplasty. N Engl J Med 1992 et ±35., 327:1329.

4. Iung B, Cormier B, Ducimetière P et al.Résultats à 5ans de la commissurotomie mitrale percutanée à partir d'une série de 606 patients. Arch Mal Coeur 1996 (89): 1591–8.

5- Song J-K, Song J-M, Kang D-H, et al. Restenosis and adverse clinical events after successful percutaneous mitral valvuloplasty: immediate post-procedural mitral valve area as an important prognosticator. Eur Heart J. 2009 May et 30(10):1254-62.

6- Wang A, Krasuski RA, Warner JJ, et al. Serial echocardiographic evaluation of restenosis after successful percutaneous mitral commissurotomy. J Am Coll Cardiol. 2002 Jan 16 et 39(2):328-34.

7- Lau KW, Ding ZP, Quek S, Kwok V, Hung JS. Long-term (36 - 63 months) clinical and echocardiographic follow-up after Inoue balloon mitral commissurotomy. Cathet Cardiovasc Diagn. 1998 Jan et 43(1):33-8.

8. Cohen DJ, Kuntz RE, Gordon SPF et al. Predictors of long-term outcome after percutaneous balloon mitral valvuloplasty. N Engl J Med 1992;327(19):1329-35

9. Chmielak Z, Klopotowski M, Kruk M, Demkow M, Konka M, Chojnowska L, Hoffman P, Witkowski A, Ruzyllo W. Repeat Percutaneous Mitral Balloon Valvuloplasty for Patients with Mitral Valve Restenosis.*Catheterization and Cardiovascular Interventions2010; 76:986–992.*

10. Pathan AZ, Mahdi NA, Leon MN, et al: Is redo percutaneous mitral balloon valvuloplasty (PMV) indicated in patients with post-PMV mitral restenosis?. JAmCollCardiol 1999 ; 34:49–54.

11.Yazıcıoglu N, Arat Ozkan A, Orta Kılıçkesmez K et al. Immediate and Follow-Up Results of Repeat Percutaneous Mitral Balloon Commissurotomy for Restenosis After a Succesful First Procedure.Echocardiography 2010;27(7):765-9

12. Aslanabadi N, Golmohammadi A, Sohrabi B, Kazemi B**.** *Repeat Percutaneous Balloon Mitral Valvotomy vs Mitral Valve Replacement in Patients With Restenosis After Previous Balloon Mitral Valvotomy and Unfavorable Valve Characteristics*. Clin. Cardiol 2011; 34(6) 401–406.

13. Iung B, Garbarz E, Michaud P, et al: Immediate and midterm results of repeat percutaneous mitral commissurotomy for restenosis following earlier percutaneous mitral commissurotomy. Eur Heart J 2000 ;21:1683–1689.

14. Palacios IF. Farewell to surgical mitral commissurotomy for many patients. Circulation1998;97:223-226.

15. Block PC, Tuzcu EM, Palacios IF. Percutaneous mitral balloon valvotomy. Cardiol Clin. 1991;9:271-287.

16.Leon MN,Harrell LC, Simosa HF et al. Mitral Balloon Valvotomy for Patients With Mitral Stenosis in Atrial Fibrillation. J Am Coll Cardiol 1999;34:1145–52

17.Fawzi ME, Hassan W, Shoukri M et al. Immediate and long-term results of mitral balloon valvotomy for restenosis following previous surgical or balloon mitral commissurotomy. Am J Cardiol 2005;96:971–975

18. Iung B, Nicoud-Houel A, Fondard O, et al. Temporal trends in percutaneous mitral commissurotomy over a 15-year period.Eur Heart J 2004;25 (8): 701-707.

19. Vahanian A, Baumgartner H, Bax J, et al .Guidelines on the management of valvular heart disease.The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology 2007.

20. Chmielak Z, Kruk M, Demkow M, Klopotowski M, Konka M,Ruzyllo W. Long-term follow-up of patients with percutaneousmitral commissurotomy. Kardiol Pol 2008 ; 66:525–530.

21. Iung B, Garbarz E, Michaud P et al. Late results of percutaneousmitral commissurotomy in a series of 1024 patients. Analysisof late clinical deterioration: Frequency, anatomic findings,and predictive factors. Circulation 1999;99:3272–3278.