

Résultats immédiats et à long terme d'une dilatation mitrale percutanée redux pour une resténose après succès de la première procédure

Immediate and follow-up results of redo percutaneous mitral balloon valvuloplasty for restenosis after a successful first procedure

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Résumé

Introduction: Depuis son introduction en 1984, la dilatation mitrale percutanée (DMPC) est devenue le traitement de choix de la sténose mitrale. Après le succès de la procédure, la majeure complication à long terme est la resténose mitrale dont le traitement fait discuter la chirurgie ou une DMPC redux.

Méthodologie: C'est travail rétrospectif observationnel mené dans l'hôpital Hédi Chaker de Sfax. Parmi 302 patients ayant bénéficié d'une DMPC, 35 ont nécessité une nouvelle DMPC durant le suivi. Dans ce travail nous avons rapporté les résultats immédiats et à long terme de cette procédure redux et nous avons comparé nos résultats (groupe 2) à ceux du premier groupe ayant bénéficié de la DMPC initialement (groupe 1).

Résultats: Les deux groupes sont comparables en terme d'âge (34 +/- 13 groupe 1 vs 32 +/-11 groupe 2) et la fréquence du sexe féminin 77 % vs 85 % (p=0,24). Il n'y a pas de différence significative entre les deux groupes concernant les caractéristiques pré procédurales: surface mitrale (0.98 +/- 0.21 dans le groupe 1 vs 1.01 +/- 0.20 dans le groupe 2), ainsi que pour le score de Wilkins et les pressions artérielles pulmonaire. Le succès immédiat de la procédure est de 85 % dans le premier groupe mais de 77 % dans le second (p =0.10). Il n'y a pas de différence dans les deux groupes en terme de complications majeures immédiates comme l'hémopéricarde ou l'insuffisance mitrale aiguë ou le décès. A long terme nous avons noté 9 cas de resténose sur les 35 patients contre 41 dans le groupe de 302 patients sans que la différence soit significative.

Conclusion: La DMPC redux est une procédure qui donne de bon résultats immédiats et à long terme sans excès de complications surtout chez les patients avec une anatomie valvulaire favorable.

Mots-clés

Dilatation mitrale percutanée, resténose, redux, rétrécissement mitral, rhumatisme articulaire aigu

Summary

Background: 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 Hedi Chaker hospital 302 patients underwent a mbv. 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.

Keywords

Mitral balloon valvuloplasty, restenosis, redo, mitral stenosis, rheumatic fever

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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 Hedi Chaker hospital, 302 patients underwent a mitral balloon valvuloplasty for the first time (group novo mbv). Among these patients, thirty five required a new valvuloplasty (group redo mbv). We compared these two groups in terms of epidemiologic, echocardiographic, procedural characteristics and mbv results.

The demographic and clinical features were obtained through medical observations.

The echocardiographic assessment of the mitral valve was performed with the transthoracic approach measuring mitral valve area using both methods: planimetry and 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 echocardiographic was realized for all patients 24 hours before mitral balloon commissurotomy in order to exclude a left atrium thrombus 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 anterograde transvenous 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 echocardiography. The aim of

echocardiography 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 echocardiographic exams were performed. Restenosis was defined as a mitral area becoming less than 1.5 cm² after initially successful mbv.

Data were presented as mean \pm SD. Comparison of hemodynamic variables was done using student t-test and chi-square test. Kaplan-Meier estimates were used to determine freedom from restenosis 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 echocardiographic characteristics:

	Group novo mbv (302)	Group redo mbv (35)	p
Age (years)	34 +/- 13	32 +/- 11	0.24
Gender female	233 (77%)	30 (85%)	0.24
male	69 (23%)	5 (15%)	
Mitral area (cm ²)	0.98 +/- 0.21	1.05 +/- 0.20	0.09
Wilkins <8	203 (67%)	22 (62%)	0.604
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 echocardiography. 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 1.74 cm² for group redo mbv (p = 0.017) and a lower level of atria pressure 13.78 mmHg for group novo mbv 16.59 mmHg for group redo mbv (p= 0.019) whereas pulmonary pressure decreased with similar rates (table 2).

Table 2: Immediate echocardiographic and hemodynamic results

	Group novo mbv (302)	Group redo mbv (35)	p
Success (%)	262 (87%)	26 (77%)	0.104
Post procedural mitral area (cm²)	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

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 group versus 19 cases in novo mbv group (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 3: Immediate complications of mitral balloon valvuloplasty

Complications	Group novo mbv	Group redo mbv
Death	2(0.6%)	0
Embolism	2(0.6%)	0
Tamponade	1(0.3%)	1(2.8%)
Severe mitral regurgitation	17(5%)	2(5.7%)

Long term follow up showed no differences between both groups (**table 4**). We noted no death in redo group in a mean follow up of 39.7 +/- 29 months. Eight patients developed restenosis in group redo mbv with 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 term 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. In our study we showed 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 shown in **table 5**.

Table 5 : epidemiologic and echographic characteristics from litterature

	Our study	Iung et al [13]	Chmielak et al [9]	Naser et al [12]	Pathan et al [10]
Number	35	53	67	25	36
Gender (f) %	85%	89%	-	-	75%
Age (years)	32	39	52	40	58
AF %	8%	11%	41%	32%	61%
Wilkins >8	38 %	-	7.5 +/- 1.3	9.56	50 %
MVA (cm²)	1.05 +/- 0.22	1.03 +/- 0.22	1.17 +/- 0.16	0.97	1.1

AF: Atrial fibrillation; MVA: mitral valve area

Procedure success was defined as a mitral valve area becoming above 1.5 cm² without significant mitral regurgitation (13,14,15). 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 valvuloplasty (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 echocardiographic 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. 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 components which 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 echocardiographic scores. That's why most of the patients used to undergo surgery. Many studies compared results of redo mbv and surgery.

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 echocardiographic characteristics and the commissural refusion as restenosis mechanism.

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Conflict of interest:

No conflict of interest to declare

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