Percutaneous mitral commissurotomy versus open mitral commissurotomy: a comparative study

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Abstract

Objective: Although many studies in medical literature are comparing percutaneous trans-septal mitral commissurotomy (PTMC) and open mitral commissurotomy (OMC), very few long-term comparative follow-ups are available. Methods: Between January 1991 and December 1997, 193 patients with isolated mitral stenosis were assigned either to PTMC (111 cases) or to OMC (82 cases). PTMC was performed in all cases with Inoue Ballon, OMC was performed with standard techniques. Categorial values were compared by chi square analysis, whereas continuous data were compared by Mann–Whitney test. Univariate survival and event free analysis (Kaplan–Meier and log rank) were performed. Recurrent stenosis was classified any mitral valve area (MVA) less than 1.2 cm² and whenever post-op. echo showed a loss more than 50% of the initial gain. Data were reported as mean ± SD. Data concerning late echocardiographic assessment were studied with linear and logistic regression analysis. Results: The two groups were homogenous as far preoperative variables as sex, mean age, MVA, echo score and incidence of left atrial thrombosis were concerned. Mean NYHA was preoperatively higher in OMC (2.79 ± 0.58) versus PTMC (2.42 ± 0.5) (P = 0.001). There was no hospital mortality in both groups. Incidence of hospital complications was similar (4/111 after PTMC and 1/82 after OMC; P = 0.3). Seven year survival: 95.41 ± 0.02 (PTMC) and 98.05 ± 0.3 (OMC) (P = 0.3) and freedom from late complications did not show statistical differences: Embolism 98.78 ± 0.01 in PTMC and 98.78 ± 0.01 in OMC (P = 0.8); Recurrent stenosis 71.89 ± 0.13 in PTMC versus 82.89 ± 0.08 in OMC (P = 0.2); Reoperation 88.43 ± 0.08 in PTMC versus 96.25 ± 0.02 in OMC (P = 0.4). A larger MVA was found in patients undergone to OMC (2.05 ± 0.35) versus PTMC (1.81 ± 0.33) (P = 0.001). Furthermore mean NYHA was lower in OMC (1.14 ± 0.3) versus PTMC (1.39 ± 0.7) (P = 0.001). Conclusions: Both techniques achieve with a low operative risk and low incidence of complications a good palliation of rheumatic mitral stenosis. Incidence of complications in the follow-up is similar. OMC allows a larger mitral valve area, a better functional recovery and a lower incidence of late mitral regurgitation.

1. Introduction

Treatment of rheumatic mitral stenosis has dramatically changed during the last few decades: Harken and Bailey [1,2] showed in the fifties that closed mitral valvotomy can successfully relieve tight, rheumatic mitral stenosis. Later, in the early seventies, with the development of perfusion and myocardial protection techniques [3], open mitral commissurotomy (OMC) evolved [3,4]. This technique, allowing direct inspection and treatment of the valve and its subvalvular apparatus, gradually replaced the closed technique. In 1984 the introduction of percutaneous trans-septal mitral commissurotomy (PTMC) [5] once again modified the therapeutic strategy of rheumatic mitral stenosis treatment, decreasing the need for surgical treatment.

Whenever a new technique was proposed for treatment of mitral stenosis, many comparative studies [6–10] were performed between series of patients with mitral stenosis treated with different techniques, trying to establish the superiority of the latest technique over the others. The main limitation of these studies was the comparison of series of patients treated in different decades, which avoided consideration of the following points: progress in echocardiography [6,8], improvements in extracorporeal circula-
tion, myocardial protection [8] and finally the significant decline of acute rheumatic fever in the Western Countries over the past decades [7,10].

PTMC is an attractive technique to relieve mitral stenosis: many papers [4,11,12] and multicenter studies [13,14] have proved its efficacy in relieving rheumatic mitral stenosis. Nevertheless, PTMC technique is a relatively `young' technique in comparison with OMC, which dates back more than two decades of experience [4,6,15]. Many questions are still open: whether PTMC allows the same long term results of OMC [8,16] and whether it has to be reserved only for high risk surgery patients [17]. In order to establish intermediate results of PTMC and OMC we compared the two techniques.

2. Materials and methods

From January 1991 to January 1998, it was a policy in our institution that patients with pure rheumatic mitral stenosis with a valvular anatomy suitable for repair referred to the Cardiology Division and underwent PTMC, and patients referred to the Cardiac Surgery Division from other Cardiology Departments underwent OMC.

Between 1991 and 1998, 193 patients with pure, rheumatic, hemodynamically significant, mitral stenosis underwent non-medical treatment at V. Monaldi Hospital: 111 patients underwent PTMC (Group A) and 82 had OMC (Group B).

Clinical data concerning mean age, sex, mean NYHA class, incidence of preoperative atrial fibrillation, left atrial thrombosis and anticoagulation in both groups are reported in Table 1.

2.1. Exclusion criteria

We considered in this study only patients with pure, isolated, rheumatic mitral stenosis; patients with more than moderate mitral, aortic or tricuspid regurgitation were excluded from the study as well as patients with hemodynamically significant aortic or tricuspid stenosis. Patients with recurrent mitral stenosis and those with clinical evidence of coronary artery disease were excluded from the study also.

2.2. Echocardiography

All patients underwent pre and postoperative (predischARGE) Doppler echocardiography with color flow mapping. Furthermore transesophageal echocardiography was performed during the procedures to assess the quality of results. Finally another echocardiographic investigation was performed at the time of the follow-up. All the echocardiographic investigations were performed in a non-blinded manner by the same team of five cardiologists.

Mitral valve area (MVA) area was calculated by the Hatle equation [18] and mitral regurgitation was graded semi-quantitatively (Absent, Mild 1+, Moderate 2+, Mean 3+ and Severe 4+) according to the method described elsewhere [19].

Mitral valve and subvalvular morphology were graded as outlined by Wilkins et al. [19]. Left atrial size and incidence of left atrial thrombosis were recorded also.

Preoperative echocardiographic data such as mitral valve area (MVA), mean left atrial size, incidence of left atrial thrombosis, Wilkins score and degree of mitral regurgitation are reported in Table 1.

2.3. Procedures

2.3.1. Percutaneous balloon mitral commissurotomy

One hundred and eleven patients, 85 females (78.8%) and 26 males (21.2%), age ranging from 16 to 74 years (mean 46.5 ± 13.8) underwent PTMC (Group A).

Transesophageal echocardiography was carried out to monitor the results. PTMC was performed by three different cardiologists using the usual techniques of right-heart catheterization, trans-septal approach and Inoue’s balloon. Transseptal puncture was performed after introduction from the right femoral vein. With the balloon in the left ventricle, the distal portion of the balloon was inflated with a large syringe attached to the proximal portion of the catheter outside of the femoral vein, and the balloon was withdrawn to fit against the mitral valve. The remainder of the balloon was then inflated, causing enlargement of the mitral orifice. Incremental balloon diameters were employed until maximal valve area was obtained.

2.3.2. Open mitral commissurotomy

Eighty-two patients, 72 females (87.8%) and 10 males
(12.2%), ages ranging from 22 to 72 years (mean 48.9 ± 10) underwent OMC (Group B).

The procedure was performed in all cases by the same group of five surgeons through median sternotomy. Under moderate hypothermic standard extracorporeal circulation (30°C), aortic cross clamping, St. Thomas cold cardioplegia and topical cooling, the mitral valve was exposed through a longitudinal left atrial incision parallel to the interatrial groove. Mitral commissurotomy was performed by sharp division of the valve commissures. The leaflets mobility was in 90% of cases by vertical incision of both papillary muscles.

Mitrail function has been evaluated intraoperatively in all cases either by hydrodynamic test and by transesophageal echocardiography.

2.4. Definition of complications

Complications were defined in accordance with the published guidelines for reporting valve related morbidity and mortality after cardiac valvular operations [21].

Procedures were considered successful if the mitral valve area increased to ≥1.2 cm² with ≤grade 2 of mitral regurgitation. Recurrent stenosis was classified for any MVA less than 1.2 cm² and whenever post-operative echocardiography showed a loss more than 50% of the initial gain. Treatment failure was considered when any of the following occurred: recurrent stenosis, embolic and/or hemorrhagic events, late sudden death, endocarditis, grade 2 or above of mitral regurgitation.

2.5. Statistical analysis

Statistical analysis was performed with SPSS (Statistical Package for Social Science) package (SPSS, Chicago, IL). Data were reported as the mean ± SD. Categorical values of the two groups were compared by chi-square or Fisher’s exact test, whereas continuous data were compared by Mann–Whitney test. Time-related analysis of late complications was calculated as percent events per year. Univariate survival and actuarial analyses were performed by Kaplan–Meier ± SE and a comparison with the log rank test. Data concerning late echocardiographic follow-up were analyzed with a multivariate analysis employing linear and logistic regression. The P value for logistic regression analysis were computed by maximum-likelihood methods. A P value less than 0.05 was considered statistically significant.

2.6. Follow-up

All patients underwent clinical examination and trans-thoracic echocardiography, performed always by the same team of physicians during the last year (at least once). The results were recorded and compared with preoperative data.

3. Results

No patient was lost to follow-up (100% complete). The follow-up ranged between 2 and 83 months (mean 37.7 ± 22.9) (total 4147 months) in Group A and between 2 and 82 months (mean 49.9 ± 28.3) (total 4096 months) in patients of Group B. The two groups were homogenous as far as total length of follow-up was concerned while mean follow-up of Group B was significantly longer than Group A (P = 0.002).

The two groups were homogenous (Table 1) as far preoperative variables as sex, mean age, MVA, mean echo score, incidence of left atrial thrombosis and degree of mitral regurgitation were concerned. Mean preop NYHA class (Table 1) was higher in Group B (2.79 ± 0.58) versus Group A (2.42 ± 0.5; P = 0.001). Incidence of preop atrial fibrillation was higher in Group B (43/82–52.4%) than in Group A (38/111–34.23%; P = 0.01) and consequently incidence of patients taking preoperatively oral anticoagulants was higher in Group B (50/82–61%) than in Group A (30/111–27.03%; P = 0.0001).

No hospital mortality was found in both Groups. As far as postoperative complications are concerned, four patients in Group A sustained postoperative complications: one patient had suffered acute pericardial bleeding during PTMC requiring emergency surgery to repair a left atrial tear and to perform a successful OMC. Three patients required surgery for severe mitral regurgitation following PTMC; one patient underwent mitral valve replacement within 24 h of PTMC, the others were operated on within the first week. Surgery was successful in all of them.

In Group B, a case of postoperative mediastinitis, treated successfully with drainage and irrigation system, was reported. No statistical differences were found between the two groups concerning postoperative complications (P < 0.30 = n.s.).

Two cases of late mortality due to sudden death were observed in Group A, leading to a 7-year survival of 95.41 ± 0.02%, meanwhile only one patient died in Group B for lung cancer during the follow-up (98.05 ± 0.01%). Nevertheless no statistical difference in terms of late survival was found between the two groups (P = 0.195 = n.s.).

Incidence of events and actuarial freedom from complications such as embolism, hemorrhage, endocarditis, recurrent stenosis and reoperation, are reported in Table 2. No statistical difference in the incidence of late postoperative complications was found between the two groups.

Postoperative functional recovery was better in Group B being the mean postoperative NYHA class (1.14 ± 0.35) lower than in Group A (1.39 ± 0.7; P = 0.01; Fig. 1).

3.1. Echocardiographic results

Results of the predischarge postoperative echocardiographic study showed that the mean MVA was significantly
higher in Group B (2.28 ± 0.33 cm²) than in Group A (1.84 ± 0.31 cm²; \( P = 0.001 \)) and the mean gain of valvular area was lower in patients undergone PTMC (0.8 ± 0.3 cm²) than in patients with OMC (1.28 ± 0.35 cm²; \( P = 0.0001 \)).

Late echocardiographic evaluation showed a persistent larger left atrial size in Group B (50.1 ± 4.4) versus Group A (47.9 ± 6.9; \( P = 0.007 \)) (Table 3).

No residual atrial septal defects or interatrial shunts were detected in both groups.

Seven patients in Group A, according to the previously reported criteria, had recurrent stenosis leading to a seven-year freedom from the event of 71.89 ± 0.13% (linearized rate 2.0%/year). In Group B, five patients (82.89 ± 0.08%; 1.5%/year) had recurrent stenosis. There was no statistical difference between the two Groups (\( P = 0.22 \)) (Table 2).

MVA was larger in Group B (2.05 ± 0.35 cm²) versus Group A (1.81 ± 0.33 cm²) (Table 3). Linear regression analysis showed a statistically significant larger (\( P = 0.001 \)) MVA in OMC patients.

The study of mitral function showed a higher postoperative mitral regurgitation in 28 cases (three grade severe, 25 grade moderate) of Group A and in three cases (grade moderate) of Group B (Table 3). Logistic regression analysis showed a significantly higher incidence (\( P = 0.028 \)) of postoperative mitral regurgitation in Group A.

Seven-year freedom from treatment failure, according to the previously reported criteria, showed a significant higher percentage of patients complication-free in Group B (73.31 ± 0.08%) versus Group A (39.14 ± 0.12%; \( P = 0.0001 \)) (Table 2, Fig. 2).

4. Discussion

Since the advent of PTMC in 1984, many studies have...
established this as a safe and effective technique to relieve rheumatic tight mitral stenosis [13,14,22].

Since either PTMC and closed mitral valvotomy share the same principle of application, the Mayo Clinic Group [23] hypothesized that analysis of long-term outcome following closed mitral valvotomy may serve as a useful surrogate to predict long-term results following PTMC. Moreover some authors have shown PTMC to be comparable or superior to closed mitral commissurotomy [9,10,16]. Furthermore a study from the University of Alabama Group [6] on an analysis of outcome events over a 20-year period in more than 300 patients undergoing closed or open mitral commissurotomy showed no difference in survival, reoperation, embolism and functional recovery between the two techniques.

The results of the above-mentioned studies lead many authors [16,19] to support the idea that PTMC should be the treatment of choice for patients with pure, non-calciﬁed, rheumatic stenosis.

Therefore, whether the results of PTMC will prove to be as effective and durable as OMC [23], will be a crucial determinant of the role of this less invasive technique. Meanwhile some criticism should be advanced on the above-mentioned studies.

Some authors [6] compare different series of patients treated in different decades regardless of the improvement of perfusion and myocardial protection techniques. Many studies, and especially those concerning patients treated surgically [6,23] more than two decades ago, are evaluating clinical variables such as functional status, freedom from valve replacement, and survival as end points without consideration of echocardiographic results. Nowadays echocardiography is the best diagnostic technique for mitral valve disease [16,18–20], no other techniques can provide the same amount of information about mitral valve morphology, commissural fusion, subvalvular apparatus and valvular regurgitation, therefore echocardiographic data should be considered in any study concerning results of mitral valve procedures.

Furthermore, many studies [7,16], concerning long term results of PTMC, include patients with recurrent mitral stenosis and/or patients with associated coronary artery disease.

The indication of the mitral procedure was varied according to the author’s experience; many performed PTMC in patients with contraindications [16,17,19] to open heart surgery; meanwhile others performed PTMC only in patients with favorable mitral morphology. Finally very few studies are performed on randomized series [7–9,16]; they have a relatively short follow-up [9] or they are performed in countries with high incidence of acute rheumatic fever [9,16] and high incidence of mitral valve procedures in the early decades of life. In clinical studies performed in patients from Western countries [16,19], including ours, the mean age of patients undergoing mitral valve procedures for rheumatic disease is above the fifth decade of life.

We performed a comparative study in order to compare the two techniques, the procedures were performed by the same team and the echocardiographic evaluation was done, although not in a blinded manner, by the same team of physicians. Furthermore the two groups were homogenous for preoperative clinical variables and for degree of involvement of the mitral valve. Finally early echocardiographic study was performed at least 48 h after the procedures in order to eliminate the effects of elastic ‘recoil’ in PTMC patients and to improve the accuracy of pressure half time measurements [24].

Our study according to others [8,16] does not report any difference between the two techniques in terms of operative mortality and morbidity and in terms of late postoperative complications. Whereas OMC is achieved either in the early postoperative period, the 7-year follow-up shows a significantly larger MVA. Moreover the number of patients with residual mitral regurgitation, albeit moderate, is higher in patients with PTMC. Functional evaluation shows a lower mean NYHA class in patients with OMC than in patients with PTMC. The reason why the orifice is not restored to normal by PTMC is, according to Frater’s findings [25], that rheumatic pathology is not conﬁned to fusion of anterior and posterior cusp tissues but also results in fusion between scallops of the posterior cusps. The posterior cusp is thereby transformed from a multiscalloped structure which expands with the dynamic mural annulus during diastole, to a stiff bar which effectively prevents the normal flow-enhancing diastolic expansion of the mitral orifice. Furthermore rheumatic disease involves subvalvular apparatus causing chor-

![Fig. 2. Freedom from treatment failure.](image-url)
nal shortening and thickening. Therefore any technique addressing only the component of commissural fusion will obtain MVA less than 2 cm² (one third to one half of normal MVA); meanwhile OMC ameliorates (to some extent) the aspect of leaflet thickening, rigidity and subvalvular apparatus. Frater et al. [25] reported, indeed, a mean MVA of 2.1 cm² following OMC for non-calci®c mitral stenosis.

Another point of discussion is the higher incidence of moderate postprocedure mitral regurgitation in patients with PTMC compared to those with OMC. Long term effects of the haemodynamic burden on the left ventricular function should be investigated.

Finally it is interesting to remember that mitral valve disease is a continuously progressive disease. Although in our series there were no statistical differences in terms of reoperation rate, Essop et al. [16] found restenosis rates of 0.08 cm²/year for PTMC versus 0.07 cm²/year for OMC.

In conclusion either PTMC and OMC obtain excellent results in the palliation of pure rheumatic mitral stenosis, achieving good relief of symptoms and low operative morbidity. Seven-year follow-up shows better clinical recovery and higher MVA in patients who have undergone OMC. Incidence of late mitral regurgitation is significantly higher in patients with PTMC. Nevertheless the incidence of other complications does not differ between the two groups. Therefore PTMC should be recommended only in high risk surgery patients. OMC remains the treatment of choice for rheumatic mitral valve stenosis with pliable leaflets.

References


Appendix A. Conference discussion

Dr Althaus (Bern, Switzerland): To my knowledge, this is the first study comparing the midterm results of percutaneous balloon with open mitral commissurotomy on the basis of a randomized series of patients. I have a question related to the inclusion criteria. Patients showing an important and progressed sclerosis of the subvalvular structures are generally considered to be bad candidates for a percutaneous procedure. Did you also enroll these subjects into your study or have they been selectively submitted directly to a surgical procedure?

Dr Renaul: We didn’t have time to make some inclusion criteria. We have to say that we selected only patients with pure rheumatic mitral...
stenosis. Patients with significant regurgitation who required an adjunctive procedure as a valvuloplasty, as a mitral, more complex repair like chordae procedures or maybe ring implantation, were excluded from the study. The inclusion criteria were possible because, as you know, we can predict preoperatively with echocardiography what we are going to do.

Dr Antunes (Coimbra, Portugal): To the best of my knowledge, this is the fourth randomized study performed recently on these two procedures and the only one that gave us superiority of surgical results, perhaps because it was triggered by a surgical team, while the other three were triggered by cardiological teams. About 6 or 7 years ago we published from our center a series of 100 patients with open commissurotomy in which we demonstrated that we could achieve mean values for valve areas of 2.9 cm², which are far above those usually published by any series of percutaneous balloon commissurotomy. We have recently reviewed that same series of patients, and the results are to be presented very soon. After a mean of 8.5 years, up to 10 years of follow-up, the valve areas remain at good values, now coming down to 2.5 cm².

There is no doubt that the open commissurotomy, which is a far more complex procedure, splits the papillary muscles, resects chordae and so on, leads to a less restrictive valve, thus positively influencing the longterm results, I hope. So, I don’t believe that there is a field for more randomized studies. I believe that they would be unethical. And I ask you whether you will still refer patients with pliable valves for percutaneous balloon valvuloplasty. Patients referred to us underwent open mitral commissurotomy directly. We didn’t refer any patient; there was no switch-over between the groups. We still keep this idea that it could be unethical, go home, as you say, with these differences. But the problem is to reach agreement with the cardiologists, who are very strong and powerful.

Dr Revuelta (Santander, Spain): Dr. Renzulli, as you know it has been demonstrated clearly that the results are quite different when the patients are on atrial fibrillation and sinus rhythm. In your nice study, most of the patients of percutaneous technique were on sinus rhythm and most of the patients of open mitral commissurotomy were in atrial fibrillation. Do you think this could be a limitation in your study?

Dr Renzulli: Of course it could be a limitation because it doesn’t take into account this particular arrhythmia problem; the arrhythmia problem is known but includes a lot of clinical variables. With these results maybe we have to look farther in the subgroup, in the subset of these patients in order to quantify and know whether arrhythmia and other situations can influence longterm results.

Dr Revuelta: Do you have any comment concerning the reoperation findings of the mitral valve? We have a good number of valve repairs and replacements after percutaneous mitral commissurotomy that failed, and we found in most of them a completely destroyed valve. Did you find any difference between the cases that you reoperated after open mitral commissurotomy versus percutaneous commissurotomy?

Dr Renzulli: We reoperated in the acute phase only three cases with mitral regurgitation and two of them had the opening in the wrong place of the commissure and valves were regurgitant. The main defect was mitral regurgitation. In the other, in the chronic phase, among the patients we operated on, there were not too many. We didn’t find any anatomical difference on the pathology findings between the two groups.