

Percutaneous Mitral Valvuloplasty in Adult Patients with Rheumatic Mitral Stenosis - Results of 200 Cases

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Abstract

This prospective study was carried out in the department of cardiology, Bangabandhu Sheikh Mujib Medical University, Dhaka and National Institute of Cardiovascular Disease (NICVD), Dhaka between July 2006 to July 2010. Total 200 patients underwent percutaneous mitral commissurotomy. Mitral valve dilatation resulted in increase in mitral valve area from $.6 \pm 0.26$ to $1.70 \pm .38 \text{cm}^2$ ($p < 0.001$). Mitral valve mean pressure gradient declined from 23.00 ± 5.38 to $6.8 \pm 2.98 \text{mmHg}$ ($p < 0.001$). The pulmonary artery systolic pressure decreased from 73.8 ± 19.30 to $29.26 \pm 11.80 \text{mmHg}$ ($p < 0.001$). Procedural success, as defined as final mitral valve area $> 1.5 \text{cm}^2$ or $> 50\%$ increase in area, was achieved in 95% patients. Serious complications occurred in 10 patients

Death occurred in two patient (1%). Minor complication such as vasovagal reaction (5%), balloon rupture without sequel (0.5%), pericardiocentesis (.5%), mitral regurgitation (3%), hypotension (1%), seizure (2%), drug reaction (1%) were also noted. The adverse hemodynamic effect of mitral stenosis may be relieved by percutaneous transvenous mitral commissurotomy but it is not without risk. The morbidity & mortality is very low in properly selected patient. This study demonstrate excellent short term clinical & hamodynamic outcome of this procedure and very low procedure related complications.

Key words: Mitral Stenosis, Balloon Valvuloplasty

Introduction

Although the standard treatment for patients with severe symptomatic rheumatic mitral stenosis who do not have anatomy requiring valve replacement has been either open or closed surgical commissurotomy, the introduction of the percutaneous balloon technique, as first described by Inoue et al¹ in 1984, has led to enthusiasm about the use of this nonsurgical procedure.² As an alternative to open or close mitral commissurotomy by surgery, percutaneous transvenous mitral commissurotomy has recently been proposed in mitral stenosis (MS).¹ Initially published reports concerned younger patients with pliable valves,^{3,4,5} but there after the efficacy of this technique was also shown in older patients with more extensive valvular disease.⁶⁻¹³ Now a days PTMC has emerged as successful alternative to surgery in many patient in our country. Rheumatic heart disease is still a major cause of valvular heart disease in Bangladesh. We conducted this prospective study to characterize the patient population undergoing the procedure at National Institute of Cardiovascular Disease (NICVD) and Department of Cardiology, University Cardiac Center, Bangabandhu Sheikh Mujib Medical University, Dhaka. The purpose of

this study was to evaluate procedural complications and mortality within the first 30 days.

Methods

A total of two hundred patients aged > 12 years (mean 25 ± 10 years) were selected from July 2006 to July 2010. The mitral valve morphology and severity of stenosis were assessed before the procedure using 2-D, M-mode and colour doppler echocardiography. Transoesophageal echocardiography was done in ten cases, where status of thrombus was not ascertained by transthoracic echocardiography. Exclusion criteria included mitral regurgitation ≥ 2 grade, significant lesions in other valves requiring surgery, infective endocarditis or left atrial thrombus. Informed consent was obtained from all selected patients.

Data Collection

Baseline data including demographic, hemodynamic, echocardiographic and functional status were collected from all patients. Data on performance of the procedure were collected including technique used, balloon types and size, maximal dilating diameter, number and duration

of inflation. Serious procedural complications, including but not limited to cardiogenic shock, myocardial infarction, cardiac perforation, cardiac tamponade, acute mitral regurgitation, systemic thromboembolism, development of pulmonary edema and the development of a neurological deficit were recorded on a standardized format was completed on all patients undergoing the procedure.

Statistical Analysis

Data were expressed as mean \pm standard deviation. Percentages were based on known values. Mortality and complication rates for patients with and without base line risk factors were analyzed by χ^2 test. Continuous variables were compared with the two sample test. A P value <0.05 was considered significant.

Results

200 cases were selected from indoor and out patient department for mitral commissurotomy. All the patients had rheumatic mitral stenosis. None had significant concomitant regurgitation or aortic valve disease. 50 out of 200 patients had symptoms of NYHA grade I, 130 had grade II-III and 20 had grade III-IV symptoms (Table-I).

Table-I

Baseline characters of study population (n = 200)

| Parameters | Features | Percentage (%) |
|----------------------|------------|----------------|
| Age : | | |
| Range | 15-50 | |
| Mean | 24 \pm 9 | |
| Sex : | | |
| Male | 38 | 17% |
| Female | 162 | 81% |
| RHD status : | | |
| MS | 110 | 55% |
| MS \pm grade -1 MR | 90 | 45% |
| NYHA status : | | |
| Class I | 50 | 25% |
| Class II-III | 130 | 65% |
| Class III-IV | 20 | 10% |
| SEC on TEE | | |
| Present | 128 | 64% |
| Absent | 15 | 7.5% |

* RHD- Rheumatic heart disease, MS- Mitral stenosis, MR- Mitral regurgitation, SEC- Spontaneous echo contrast, NYHA- New York Heart Association, TEE- Transesophageal Echocardiography.

The mean MVA before the procedure was 0.6 ± 0.26 cm². The mean LA size has 45.93 ± 7.8 mm. All the patients had significant pulmonary hypertension with mean PASP 73.8 ± 19.30 . The mean 2-D echocardiographic score of the patients were 5.7 ± 1.76 (Table-II).

Table-II

Showing echocardiographic parameters of study population (n=200)

| Parameters | Pre-BMV | Post-BMV | P value |
|---|------------------|-------------------|---------|
| Mitral valve area (cm ²) | .6 \pm 0.26 | 1.70 \pm .38 | <0.001 |
| Mean mitral gradient (mmHg) | 23.0 \pm 5.38 | 6.8 \pm 2.98 | <0.0001 |
| Pulmonary artery systolic pressure (mmHg) | 73.8 \pm 19.30 | 29.26 \pm 11.80 | <0.001 |
| Left atrial size (mm) | 45.93 \pm 7.8 | 37.32 \pm 3.21 | >0.5 |
| 2D echo score | 5.7 \pm 1.76 | 4.8 \pm 1.23 | >0.5 |

After balloon dilatation, pulmonary artery systolic pressure decreases from 73.8 ± 19.30 to 29.26 ± 11.80 ($p < 0.001$). Mitral valve area increases significantly from 0.6 ± 0.26 to $1.70 \pm .38$ ($p < 0.001$). Mitral valve mean pressure gradient decreased from 23.0 ± 5.38 to 6.8 ± 2.98 mmHg ($p < 0.0001$). Left atrial size reduced from 45.93 ± 7.8 to 37.32 ± 3.21 mm ($p > 0.5$) which is not statistically significant (Table-II). Technical success defined as a resultant mitral valve area >1.5 cm² or 50% increase in MVA was achieved in 95% cases.

The patients were categorized according to the pre & post procedure MVA (Table III). Post procedural MVA were excellent with similar rate of complications.

Table-III

Comparison of mitral valve area of the study population (n=200)

| No of patients | Pre procedural MVA(cm ²) Mean \pm SD | Post Procedural MVA(cm ²) Pre Mean \pm SD | P value |
|----------------|---|--|---------|
| 62 | 0.59 \pm 0.19 | 1.98 \pm 0.42 | |
| 88 | .69 \pm 0.29 | 1.88 \pm 0.19 | <0.01 |
| 18 | .63 \pm 0.49 | 1.79 \pm 0.34 | |
| 32 | .67 \pm 0.21 | 1.69 \pm 0.51 | |

Table-IV
Complications of the study patients (n=200)

| Parameters | Number | Percent (%) |
|-------------------------------------|--------|-------------|
| Minor complications | | |
| 1. Mitral regurgitation >II <III | 2 | 1% |
| 2. Vasovagal reaction | 3 | 1.5% |
| 3. Balloon rupture without sequelae | 1 | 0.5% |
| 4. Drug reaction | 2 | 1% |
| 5. CPR required | 2 | 1% |
| 6. Arrhythmias requiring treatment | 1 | .5% |
| 7. Prolonged hypertension | 2 | 1% |
| 8. Seizure | 4 | 2% |
| 9. Significant hematoma | 2 | 1% |
| Major complications | | |
| 1. Cardiac perforation | 2 | 1% |
| 2. Cardiac tamponade | 2 | 1% |
| 3. Emergency cardiac surgery | 3 | 1.5% |
| 4. Acute MR (grade >3) | 4 | 2% |
| 5. Pulmonary edema | 7 | 3.5% |
| 6. Cardiogenic shock | 6 | 3% |
| 7. Death within 24 hours | 2 | 1% |

Major complications include need for mitral valve replacement in the hospital, required in 2 cases. Cardiogenic shock developed in 6 cases and 2 patient died 24 hours within procedure. Cardiac perforation leading to cardiac tamponade occurred in 2 cases.

Complication

Table IV and V shows the incidence of minor and major complications of the procedure. Minor complications included mitral regurgitation grade >II <III in 2(1%) cases, vasovagal reaction in 3(1.5%), balloon rupture without sequel in 1(.5%) cases, other minor complications included arrhythmias requiring treatment, prolonged hypotension, seizure and significant hematoma also occurred.

Major (serious) complications like cardiac perforation in 2(1%) patient, cardiac tamponade in 2(1%), emergency cardiac surgery in 3(1.5%), acute mitral regurgitation grade >3 in 4(2%) patient, pulmonary oedema occurred in 7(3.5%) pt. cardiogenic shock occurred in 6(3%) patient and two patient (1%) died within 24 hours of the procedure.

Follow-up

Every patient was followed up during hospital period and then after one month clinically and echocardiographically.

Table-V
Comparison of in hospital complications

| Parameters | Babie (n=76) | | Palaces (n=100) | | Levine (n=105) | | Ruiz (n=281) | | NHLBI (n=735) | | Our Study (n=200) | |
|------------------------|--------------|-----|-----------------|----|----------------|----|--------------|-----|---------------|----|-------------------|----|
| | n | % | n | % | n | % | n | % | n | % | n | % |
| Death | 1 | 1.3 | 1 | 1 | 1 | 1 | 3 | 1.1 | 20 | 3 | 2 | 1 |
| Severe MR | 2 | 2.6 | 1 | 1 | NR | | 4 | 1.4 | 24 | 3 | 4 | 2 |
| Temponade/ Perforation | NR | | 2 | 2 | 2 | 2 | 14 | 5 | 32 | 4 | 2 | 1 |
| Embdic events | 3 | 3.9 | 2 | 2 | 2 | 2 | 4 | 1.4 | 21 | 3 | 0 | |
| Left to right | NR | | 20 | 20 | 21 | 20 | 45 | 16 | 71 | 10 | NR | NR |

Discussion

Ballon mitral valvuloplasty (BMV) with inoue device has demonstrated high efficacy and improved procedural success compaired with other techniques.^{13,27} Several studies have documented the beneficial effect of BMV for the relief of symptoms in adult patients with acquired mitral stenosis.^{2,4,5,6,22} A comparison of the in hospital complications that occurred in our study with those of other reports (Table-V) revealed that in 200 patients death

rates was 1%, severe MR was 2% and cardiac tamponade and/or perforation occurred in 1% cases.

Of the surgical approaches to the treatment of patients with severe symptomatic mitral stenosis, closed commissurotomy is probably we most like than percutaneous balloon commissurotomy. Mortality rates after surgical closed commissurotomy range from 0.5% to 7.6%.^{9-12,22,23} Comroerford and colleagues¹⁵ reported results of closed mitral commissuroitomy in 654 patients.

The overall operative mortality rate was 2.97%, and the incidence of mitral regurgitation severe enough to require re-operation within 30 days was 0.6%.

The results reported in the Balloon Valvuloplasty Registry are comparable to those previously reported in patients undergoing surgical closed mitral commissurotomy. It is interesting that previous reports of patients undergoing closed commissurotomy have noted that operative mortality was highest in older patients as well as those with opening snap by physical examination and in those with mitral valve calcification.^{10,24} We have noted similar findings in patients undergoing percutaneous balloon mitral commissurotomy.

Although percutaneous balloon mitral commissurotomy is difficult to compare with open surgical commissurotomy the comparison is never the less of inserts. Operative mortality varies from zero to 12%,^{13-15,18} with some authors noting a lower mortality in patients receiving cold cardioplegic arrest¹⁵ and others having seen no difference.²⁵ The incidence of the development of severe mitral regurgitation appears to be rare,¹⁵ but it must be remembered that, when a sub optimal result occurs with open commissurotomy, the mitral valve is replaced with a prosthesis. Cerebrovascular accident and transient ischemic attacks are uncommon.¹³

We have described the results of percutaneous balloon mitral commissurotomy in 200 patients undergoing the procedure in two institutions in Bangladesh. Death occurred in 0.1% patients during the study period.

Although percutaneous balloon mitral commissurotomy appears effective at relieving the hemodynamic effects of rheumatic mitral stenosis, it does have important risks. Complications of the procedure do appear to be importantly affected by the experience of the individual center.

Therefore, an improperly selected patients treated in experienced centers, this procedure can be done with low risk and excellent short-term outcome.

Patients best suited for this procedure include those of younger age without evidence of left atrial possible thrombus by standard two-dimensional echocardiography, those with a lower echo score and considered to have surgical risk.

Transthoracic echocardiography is less sensitive detector of left atrial thrombi that can be correctly diagnosed by transoesophageal echocardiography. In our series we have excluded left atrial thrombi by trans oesophageal

echocardiography without any event. We performed PTMC of all our patients without any thrombo-embolic complications.

From our series, percutaneous transvenous mitral commissurotomy (PTMC) seems to be safe and effective treatment in a wide range of Bangladeshi patients with mitral stenosis, and this appears to be an alternative to surgery in patients who are good candidate for commissurotomy. The greatest improvement of valve function concomitant with the lowest incidence of complications is to be expected.

Conclusion

Percutaneous transvenous mitral commissurotomy is an established non-surgical procedure for the treatment of symptomatic mitral stenosis but it is not without risk of complications. It can be safely done in patient with severe intractable heart failure, pregnancy with mitral stenosis and also in severe disabled bed bound patients with poor general conditions.

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