BALLOON MITRAL VALVOTOMY: IMMEDIATE OUTCOME OF 300 PROCEDURES

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Three hundred patients with severe symptomatic rheumatic mitral stenosis underwent balloon mitral valvotomy (BMV) at Queen Alia Heart Institute (QAHI) during the period between May 1988 to April 1994. The clinical characteristics, immediate procedural outcome, hemodynamic variables, two-dimensional echocardiography and Doppler-derived mitral valve area (MYA) were retrospectively analyzed. There were 226 females and 74 males with a mean age of 34.4 ± 13.5 years. Sixty-four patients (21%) were in atrial fibrillation. Sixteen patients had prior surgical mitral commissurotomy, 3 patients (1%) had prior aortic valve replacement (A V R), 22 patients (7.3%) had grade II mitral regurgitation (MR), 54 patients (18%) had associated grade II or less aortic regurgitation (AR), 1 patient (0.3%) had history of systemic embolism, and 2 patients (0.7%) were pregnant. All patients had mitral valve echo score < 10/16. A total of 286 patients (95%) had successful outcome and 270 (90%) had optimal result. In 16 patients (5%), the result was suboptimal and 14 patients (4.6%) had major complications before or after attempted balloon dilatation. One patient died of septicemia 5 days after the procedure. Minor complications occurred in 117 patients (39%), most of which did not require immediate special therapeutic measures and were well tolerated. The two most common minor complications were de novo or increased MR (21%) and tiny or small angiographic atrial septal defect (11%). BMV is a sufficiently safe and effective procedure justifying its use as the procedure of choice in patients with severe mitral stenosis and low echo score.

IN OUR PRACTICE every sixth patient seen in the clinic and every fourth one undergoing cardiac catheterization at our institute primarily have rheumatic heart disease. Surgical open mitral valvotomy comprised of 10% of the open heart surgery performed in our institute during the mid-1980s. Forty years after successful surgical relief of mitral stenosis, Inoue made commissural splitting possible without breaching the integrity of the thoracic cage. In this retrospective study, we report the immediate outcome of the first 300 balloon mitral valvotomies (BMV) using the percutaneous double-balloon technique introduced by Al-Zaibag! which proved to be comparable to the Inoue technique.2,3

Methods

Study Population

Between May 1988 and April 1994, 391 patients with severe symptomatic mitral valve stenosis presented to Queen Alia Heart Institute (QAHI). Three hundred patients (76.7%) underwent BMV; 226 (75.3%) were females and 74 (24.7%) were males with a mean age of 34.4 ± 13.5 years (range, 8 to 73 years). All were symptomatic; 39% were in New York Heart Association (NYHA) class II, 51% in class III and 10% in class IV. Sixty-four patients (21.3%) were in atrial fibrillation, and 236 (78.7%) were in normal sinus rhythm. Sixteen patients (5%) had previous surgical mitral valvotomy. There was prior aortic valve replacement in 3 patients (1%). Twenty-two
patients (7%) had grade II mitral regurgitation and 54 patients (18%) had grade II aortic regurgitation. Ten patients (3%) had remote history of systemic embolism and were on adequate long-term oral anticoagulant. Two patients (0.7%) were pregnant (2nd trimester).

Two-Dimensional (2D) Echocardiography and Doppler Study

All patients underwent 2D-Doppler studies before and after the procedure. Mitral valve area (MY A) was calculated using the combination of 2D-echocardiography (planimetry) and Doppler echocardiography (pressure half-time).

The presence or absence of left atrial thrombus was based on the transthoracic 2D-echocardiography study (TEE).

A mitral-valve echocardiographic score was derived according to the criteria of Wilkins and colleagues, in which a maximum of 4 points was assigned according to the severity of each of the following four characteristics: mitral valve leaflet calcification, impaired valve leaflet mobility, valve leaflet thickening, and subvalvular disease (0 indicates normal and 4 the most severe abnormality). The overall echocardiographic score was derived from the sum of the above four separate scores. This score was adopted after September 1988.

Hemodynamic Data and Oxymetric Measurements

Right and left heart pressures, as well as oxygen saturations in the different cardiac chambers, were recorded and measured before and after the procedure. Pre- and post-cardiac outputs were calculated using a computerized Fick's method.

Patient Exclusion

Patients with left atrial thrombus > grade II/LY mitral or aortic regurgitation or with an echo score of mitral valve > 10 were not considered candidates for BMY.

Procedure

All patients who underwent right and left heart catheterization within 6 weeks of the index procedure were re-admitted one day prior to the procedure where detailed echocardiographic and doppler examinations were carried out to reassess the mitral valve area, left atrial size, freedom from thrombus, and the echo-score. Written informed consent was obtained and two units of blood were crossmatched.

On the day of the procedure, the patient fasted and the groins were shaved. The patient was premedicated with meperidine 50 mg (Pethedine) and promethazine 25 mg (Phenergan) intramuscularly on call to the catheterization laboratory. The right femoral vein and left femoral artery were cannulated. Pulmonary artery angiogram with levophase was obtained to delineate the left atrial borders in anteroposterior and lateral views for road mapping.

Through the right femoral vein, a Mullins transseptal dilator/sheath loaded with a Brockenbrough transseptal needle was introduced transseptally into the left atrium where the dilator and needle were pulled out. The left heart catheter was advanced to the left ventricle and simultaneous pressures were recorded across the mitral valve to estimate the transmitral gradient. Then, heparin 200 units/kg body weight was given intravenously. A preshaped catheter was introduced through the sheath and advanced into the left ventricle through the mitral valve. A preshaped extra-stiff J exchange wire was placed into the apex of the left ventricle and maintained in position while withdrawing the sheath and catheter; then over the exchange wire, a twin balloon was guided transseptally to straddle the mitral valve. Inflations were made until the waist disappeared and under central aortic pressure monitoring. The balloons were withdrawn and replaced by a catheter to record a pull-back pressure from the left ventricle to the left atrium for the final transmitral gradient. Left ventricular, right upper pulmonary vein angiograms (to detect and size the atrial septal defect), final right and left pressures, and saturations were obtained. Heparin was reversed by intravenous protamine.

The catheters were pulled out and the patient was sent to the floor. The following day, detailed echodoppler examination was repeated to measure the MY A and left atrial diameter to quantitate mitral regurgitation and to rule out small pericardial effusion.

Definitions

Our definitions for optimal success, suboptimal success, and major and minor complications are as
follows: (1) optimal success: final MV A> 1.6cm² and transmitral gradient < 8 mm Hg; (2) suboptimal success: final MV A between 1.2 to 1.5 cm² (but increased more than 40% of the baseline) and transmitral gradient < 10 mm Hg; (3) major complications: cardiac chamber or great vessel perforation, hemodynamically significant acute severe mitral regurgitation or pulmonary embolism, cerebrovascular accident, fatal sepsis and complicated infective endocarditis; and (4) minor complications: de novo or increased mitral regurgitation to ~ grade II, small angiographic atrial septal defect, uncomplicated deep vein thrombosis, non hemodynamically significant pulmonary embolism, peripheral systemic embolism, transient cardiac arrhythmia, uncomplicated infective endocarditis, and small pericardial effusion without tamponade detected on the next day 2-D follow-up echocardiogram.

Statistical Analysis
Values were expressed as mean ± 1 standard deviation. Pre- and post-BMV measured variables were compared by student's t-test. A P value of 0.001 or less was considered significant.

Results

Procedure Outcome
A total of 286 patients (95%) had successful outcome. In 270 (90%), the result was optimal and in 16 patients (5%) the result was suboptimal.

Hemodynamic Variables
The mean transmitral pressure gradient dropped from 19.6 ± 7.6mm Hgt03;: 2.4mmHg (P < 0.001). The mean pulmonary artery pressure

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Two-DimensionalEchocardiography and Doppler Results
The mean MV A increased from 1.0 ± 0.2 cm² to 2.1 ± 0.6 cm² (P < 0.001) and the mean left atrial diameter decreased from 46.8 ± 7.1 mm to 43.2 ± 0.7 mm (P < 0.001).

Complications

Major complications: Fourteen patients (4.6%) developed major complications (9 patients had cardiac tamponade due to cardiac chamber or great vessel perforation, 1 had significant mitral regurgitation [grade III], 3 had cerebrovascular accidents, and 1 had fatal sepsis). All patients with cardiac tamponade needed emergency surgical intervention and the site of perforation was documented at surgery (2 IVC-RA junction, 4 left atrium, 3 left ventricular apex). In the three patients who developed cardiac tamponade after successful balloon dilatation because of left ventricular apical perforation, the patients only required surgical suturing. In the 6 patients who had cardiac tamponade prior to successful dilatation, two needed mitral valve replacement and the other four required open mitral commissurotomy. Only one patient developed significant mitral regurgitation (grade III) due to torn anterior mitral leaflet and underwent mitral valve replacement which was performed the next day. One patient died of sepsis 5 days after a successful procedure. Three patients had nonfatal cerebrovascular accidents.

Minor complications: Minor complications occurred in 117 patients (39%), most of which did not require special therapeutic measures and were well tolerated. Details are shown in Table 2.

Effective Baloon Dilatation Areal Body Surface Area (EBDA/BSA)

Although Group I with 78 patients (26%) had the lowest EBDA/BSA while Group II with 77 patients (25.7%) had the highest EBDA/BSA in the range, the mean change in the mitral valve area was not found to be significantly different (P < 0.1); yet, the group of patients whose end result

Discussion

In the early cases, two balloons were advanced over two wires through two transseptal punctures, via the same vein with cannulation of the adjacent right femoral artery. The procedure evolved to a safer, less time consuming and less cumbersome method, using two balloons mounted on one shaft (twin balloon with pigtail end) over one wire through one transseptal puncture from the right femoral vein and with the left femoral artery cannulated for retrograde left heart catheterization and monitoring purposes. Two intermediate steps in evolution were the use of two veins (right and left femoral for the two transseptal punctures to lessen vein damage) and the use of one transseptal route to deliver two wires through a special (Brock transseptal exchange) catheter.

In vivo and in vitro studies showed that BMV causes commissural splitting in a manner analogous to closed surgical commissurotomy with an increase in the MV A, even in patients with severe mitral valve thickening that has minimal change in the degree of mitral regurgitation. The likelihood of causing significant mitral regurgitation is not greater than in closed mitral valvotomy, R and the initial improvement is maintained at intermediate-term follow-up, especially in the subset of patients with an echo score of 8 or less. Also, the long-term follow-up is not different from that of closed and open surgical valvotomy.

Our results are in conformity with the established results of the double-balloon technique which have been shown to be comparable to the Inoue technique.

It is noteworthy that the major complications occurred mainly in the first 60 cases, coincident with the ascending limb of the learning curve for the transseptal puncture and before the introduction of the twin balloon mounted on a shaft with a pigtail end and prior to detailed evaluation of the mitral valve by echo cardiography using the 16-point score. The credit goes to the standby surgical team whose quickness saved the few patients requiring emergency surgery in those early days, thus, making this report free from procedural mortality. We concur with the editorial comment of John W. Kirklin that if the institution performing BMV has a low prevalence of untoward events associated with the procedure itself, BMV would appear to be the initial procedure-of-choice in patients with important mitral stenosis with mobile leaflets and minimal chordae thickening.

Conclusion

This procedure offers palliation of stenosed mitral valve without resorting to thoracotomy, with low morbidity and shorter hospital stay.

It is important to note that this subset of patients was comprised of 76.7% of the patients with severe mitral stenosis who need surgical relief in the era prior to the introduction of BMV in our developing country. Thus, extrapolation of our results to the industrialized world where patients are older and the cicatrization of the mitral valve is advanced should be made with caution.

References


