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A RANDOMISED STUDY TO COMPARE POST BALLOON MITRAL VALVOTOMY (BMV) FAILURE VERSUS ELECTIVE MITRAL VALVE REPLACEMENT (MVR) FOR MITRAL STENOSIS (MS).

Cardiovascular and Thoracic Surgery

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ABSTRACT

A randomised study comparing post ballon mitral valvotomy (BMV) failure versus elective mitral valve replacement (MVR). The patients were randomised into 2 groups and evaluated. Emergency MVR following BMV failure has higher risk as compared to elective MVR in patients of rheumatic mitral stenosis.

KEYWORDS

Mitral stenosis, Mitral valve replacement, Balloon mitral valvotomy, rheumatic heart disease, mortality.

Aim :
To compare the outcome of patients undergoing MVR post BMV failure versus those undergoing elective MVR for anatomically similar lesions.

Introduction :
In India, Rheumatic heart disease (RHD) remains to be a major health problem affecting patients of all age groups and belonging to different strata of the society. Valve surgery, especially mitral valve, remains the most frequent operation in cardiac surgery in any teaching hospital. Rheumatic MS remains the most common valvular heart disease in Indian scenario. Other causes of MS include congenital MS, mitral annular calcification and infective endocarditis (IE). No cure is available for RHD and definitive treatment remains relief of mitral valve obstruction.

The surgeries for mitral valve have been Open mitral commissurotomy (OMC), Closed mitral commissurotmy (CMC) and MVR (1), (2), (3), (6). With the advent of BMV, there has been great enthusiasm for its use in MS (4). However ultimately in the advent of restenosis, patient ultimately requires MVR (5). Improper selection of patients or unexpected anatomy may result in BMV failure (7). In such scenarios, patients end up in emergency situation. In pre procedure period, had the anatomy been correctly assessed, these patient could have been offered MVR as a primary modality of treatment. The study aims to compare the outcome for MVR done for elective patients as against those of BMV failure.

Materials and methods :
This is a retrospective study comparing outcomes of patients with failed BMV undergoing MVR and patients undergoing MVR as primary modality of treatment. 30 cases of failed BMV (Group A) referred to us for management were studied. The cases spanned over 8 years from 2010 to 2017. Records were collected and studied from patient's admission to discharge. The findings were compared with patients directly undergoing MVR (Group B) during the same above mentioned period, a total number of 161. These were patients of RHD with pure MS as the valvular lesion similar to Group A patients.

Inclusion criteria :
Group A : all failed BMV patients referred for management from 2010 to 2017.

Group B : RHD with severe MS undergoing MVR from 2010 to 2017.

Exclusion criteria :
1. Patients undergoing MVR having other associated lesions.
2. Patients undergoing emergency MVR for any other reason.

All patients were analysed and studied with following parameters in mind :

1. Preoperative New York Heart Association (NYHA) class

Group A patients were in NYHA class 3 or 4 dyspnea as compared to group B were in class 2 dyspnea.

2. Requirement of pre operative inotropic support

Depending upon preoperative status, the requirement of support varies. This reflects on the haemodynamic status and has an impact on the immediate outcome of the surgery.

3. Intra operative findings and supports while coming off bypass and any adverse events.

Many times intraoperative findings had discrepancy with pre operative echo reports.

4. Post operative requirement of inotropic supports and ventilation.
The more the requirement of supports while coming off bypass, poorer the outcome. Requirement of ventilation in itself is a morbidity.

5. Duration of icu stay.

Arrhythmias, low cardiac output, sudden arrest and pulmonary edema affect the future course of the patient. Prolonged icu stay is an adverse effect

6. Duration of indoor stay.

Increased hospital stay increases occupancy, strain on manpower usage and increase in cost.

7. Complications.

Various complications are possible in open heart surgery and its frequency increases with situations.

8. Mortality.

In elective valve surgery, mortality upto 5% is accepted. However both group patients are admitted for elective procedures. Hence, seriously thought should be given to increase in mortality in either groups.

Results :
All the variables in the above study were compared amongst the 2 groups and statistically analysed using various statistical tests. The mean value for all parameters were calculated for each group and compared. T test was applied.

Pre op NYHA class varied in group A from 3-4 (3 – 25 patients, 4 – 5 patients) mean being 3.17, while all patients in group B had NYHA

class 2. The significance factor being 0, difference was statistically very significant.

Preop inotropic support was required in 29 out of 30 patients while none of group B patient required support. This is statistically significant.

The bypass time in group A patients varied from 59 to 167 minutes with a mean of 87.40 mins. The bypass time in group B varied from 52 to 125 mins with a mean of 91.57 mins. The mean difference being 4.17, statistically insignificant.

The cross clamp time in group A patients varied from 40 to 127 mins, with a mean of 55 mins, while cross clamp time of group B patients was in range of 36 to 73 mins with mean of 60 mins. It was statistically insignificant difference.

Cardiplegia required for patients in group A was 2 to 5 with mean of 2.43 and in group B was 1 to 3 with mean of 2.62, mean difference of 0.19 which was statistically insignificant.

Post operative inotropic supports required in 90% caases in group A against 74% in group B. difference being 15.47%. the difference is statistically significant.

Duration of ICU stay for group A patient varied from 2 to 5 days with mean of 2.73 and group B was 1 to 7 days with mean of 1.87. Mean difference of 0.96 had significance factor of 0.002 which is significant. Total duration of indoor stay was 10 to 16 days for group A (mean of 11.9) and group B was 7 to 20 days (mean of 10.34). The mean difference is 1.56. Significance factor of 0.021 which is quite significant.

Mortality in group A was 10 % as against 3.7% in group B.

Discussion :

This study includes 30 patients in group A and 161 patients in group B. So there is an apparent sample size mismatch between the 2 groups but this is done because of the fact that we wanted to include the cases in both groups starting from the year 1999 and this also avoids the selection bias for group B, which would have happened had we taken only 30 patients.

We have studied the morbidity and early mortality in both groups as well as the parameters mentioned above. We compared our studies with some other studies. In the study done by Farhat et al the mortality in patients undergoing BMV was 0.4%. These patients had undergone emergency surgery for failure of BMV. 4.6% of all patients needed emergency MVR. So the mortality in post BMV failure patients was 8.69%. Similarly the mortality for post BMV failure MVR in a study conducted by Lung et al was 8.82 % and that in study conducted by Chen and Cheng et al was 8.57%.

In our study the mortality in post BMV failure MVR is 10 % which is comparable to other studies. Bessel et al reported mortality rate of 4.7 % in elective MVR as compared to 3.7% in our group B. As compared to the Society of Thoracic surgeons National Cardiac Surgery Database (USA) average mortality was 3.2% as compared to 3.7% in our study.

Conclusion :

Post BMV failure MVR is a procedure with significantly higher risk as compared to direct MVR. The mortality difference between the 2 groups is statistically significant. The intra operative course in the form of cardioplegia required, bypass time and cross clamp time are not statistically different. The adverse events is more in post BMV failure MVR as expected in any emergency situation. The causes for BMV failure as noted by intra operative findings are under estimating the subvalvar score in pre procedure 2D echo and limitations in preop investigations to evaluate the sub valvular apparatus and valve score accurately. There is a need for a more specific diagnostic modality which can accurately score valve preoperatively so that the failure rate of BMV can be brought down. So till the time such a perfect diagnostic modality is not available, borderline doubtful patients should be treated with MVR rather than attempting BMV.

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