New Approach in Emergency Operation for Redo Mitral Valve Replacement: Is it Justified?

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Abstract

Background- With the progressive aging of western populations, cardiac surgeons are faced with treating an increasing number of critically ill and elderly patients. Controversy exists as to whether the ordinary mid-sternotomy approach to these malfunctioning mitral valves will do the job or a new right thoracotomy approach without cross clamping the aorta is better suited to take care of the problem. The potential to avoid mid-sternotomy surgery in redo patients with little chance of survival and poor quality of life postoperatively would spare unnecessary suffering, reduce operation mortality, and enhance the use of resources.

Methods- We managed 52 cases of severely ill patients admitted to our department on referral from rural areas with malfunctioning prosthetic mitral valves from July 15, 2000 through June 20, 2002. Four patients were women. Preoperatively most of the patients were not moribund, but 67% had hemodynamic instability and 23% experienced cerebral ischemia. All the patients had prosthetic mitral valves. Hospital mortality and morbidity models, based on our overall experience with 52 patients operated on for malfunctioning mitral valves during the period of the study, were developed by means of multivariate logistic regression with preoperative and intraoperative variables used as independent predictors of outcome.

Results- Overall hospital mortality was 14%. There was no intraoperative mortality. All the patients who survived had one or more postoperative complications. Mean hospital stay was 17 days with an average of 11 days and median of 10 days in the intensive care unit. All of the survivors (6 patients) discharged from the hospital were able to function independently and their survival at 6 months was 100%. Statistical analysis of the overall experience with this new operation for malfunction of prosthetic mitral valves confirmed that via right thoracotomy, the cross - clamping of the aorta is the most important independent patient risk factor associated with 30-day mortality and morbidity.

Conclusion- Operations for critically ill patients involve increased hospital mortality and morbidity. Short-term survival is unfavorable and is associated with a poor quality of life. With additional corroborative studies to endorse the present findings, the use of right thoracotomy approach to have access to malfunctioning mitral valve without the cross-clamping of the aorta remains a substantiated concept. In the context of these critically ill patients, the hypothesis that right thoracotomy approach without the cross-clamping of the aorta should be advocated for surgical intervention to save these patients and to conserve resources is supported by the presented data. **(*Iranian Heart Journal.* 2002, 2003; 3(2&3): 38-43)**

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With important demographic changes taking place in cardiac surgical practice, critically ill patients are more frequently undergoing complex operations.[1-4] Controversy exists as to whether the classical mid-sternotomy

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approach with cross-clamping of aorta is better tolerated by patients compared to right thoracotomy without the cross-clamping of the aorta. Published studies on elective coronary bypass graft and valve surgery reveal that elderly and critically ill patients should not be denied these procedures, although the treatment of older patients involves increased hospital mortality and morbidity, and longer hospital stays.[1-3]

Malfunctioning prosthetic mitral valve is generally an acute condition and mortality from this remains high despite important advances in operative therapy. Recent reports indicate that cardiac function is a risk determinant of early results after emergency valve surgery. This study reviews our experience with a particular subset of patients with malfunctioning prosthetic mitral valves referred to our center.

Patients and Methods

We reviewed the records of 7 malfunctioning mitral valve patients who underwent surgery via right thoracotomy from July 15, 2000 to June 20, 2002. They represented 13% of 52 operations for prosthetic valve malfunction performed in the same period.

The clinical characteristics of these patients, consisting of 4 women and 3 men are presented in Table I. The mean age of patients was 43.8 years (median 33; range 20-55 years). All the patients had associated diseases. On admission, no patient was moribund and none required external chest compression for cardiopulmonary resuscitation, although 67% of the patients had hemodynamic instability. One patient was unconscious on admission, and 2 had a preoperative stroke. Renal and respiratory insufficiency was present before admission in 29% and 70% of the patients, respectively. A total of 57% of the patients had a reduction in renal function preoperatively, which was largely attributable to hemodynamic instability.

Ischemia was encountered in only one patient. Moderate to severe chronic cardiac failure was present before admission in 29% of the subjects.

Table I. Clinical data:

Incision / Clinical data	Right Thoracotomy 7	Median Sternotomy 45
Mean age± SD (range)(y)	43.8±3.3 (20-55)	41.2 ±2.9 (22-58)
Female	4(57%)	35(18%)
Hypertension	2(28%)	6 (13%)
Smoking	3(43%)	10(22%)
Diabetes	0	6 (13%)
PVD	1(14%)	3(7%)
Angina	1(14%)	3(7%)
COPD	2(28%)	9(20%)
Cardiac Insufficiency	6 (86%)	42 (93%)
Chest Pain	7 (100%)	42 (93%)
Hypotension	5 (71%)	33 (73%)
Mitral valve regurgitation	2 (28%)	28 (62%)
Pericardial effusion*	3 (43%)	31(69%)
Cardiac tamponade †	1 (14%)	12 (27%)
CPR	1 (14%)	6 (13%)
Myocardial Ischemia	1(14%)	4 (9%)
Oligoanuria	3 (43%)	8(18%)
Visceral Ischemia	1 (14%)	8 (18%)
Coagulation disorder	6 (86%)	44 (94%)

SD indicates standard deviation; PVD, peripheral vascular disease; COPD, chronic obstructive pulmonary disease; CPR, cardiopulmonary resuscitation.
* Preoperative noninvasive diagnosis of pericardial effusion
† Pericardial effusion with hemodynamic significance

No patient was refused surgery because of age or concomitant disease. On admission, all the patients had severe coagulation disorders.

Platelet aggregation (aggregometry) and hemostasis (thromboelastography) were markedly reduced in all the patients. In addition, variable degrees of thrombocytopenia, low levels of the thrombin inhibitor angiotensin III, and coagulation factors (fibrinogen, V, VII, VIII, and IX), and high levels of plasmin degredation of cross- linked fibrin (D-dimer) were measured.

All procedures were performed with emergency status within 24 hours after the initial onset of dyspnea on exertion and chest pain, and all the patients were operated on within 4 hours of their arrival.

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The operative techniques used are summarized in Table II.

Table II. Operations

	Right Thoracotomy	Median Sternotomy
No. of patients	7	45
Aortic cross- clamping	0	45(100%)
Mean myocardial ischemic time± SD (range, min.)	0	65±33 (43-127)
Mean pump time ±SD (range, min.)	71±27 (45-118)	120±43 (63-260)
Associated Procedures		
CABG	1(14%)	1(2%)
Aortic valve surgery	0	2(4%)

SD indicates Standard deviation; CABG (Coronary artery bypass grafts)

Operative Technique

All the operations in this series of 7 cases were performed through right thoracotomy incision according to previously described standard surgical techniques. In the last case, ascending aortic cannulation was done instead of femoral cannulation, which was due to a history of recent bilateral femoral artery embolectomy procedure. Preoperative coagulation disorders were aggressively treated from the time of admission with the aid of blood bank products, antithrombin III, aprotinin and coagulation factor concentrates.

Continuous ultrafiltration during CPB was occasionally used as was a cell saver device (Haemonetics Corp., Braintree, Mass.). Arterial pressure monitoring lines were routinely placed in radial arteries. Systemic anticoagulation for CPB was accomplished with heparin at an initial dose of 3 mg/kg body weight. Adequate heparinization for CPB was assessed with the activated clotting time (Hemochron FTK – ACT; International Technique Corp., Edison NJ), with further dose of heparin administered as required so as to maintain an activated clotting time greater than 750 seconds. At the end of the procedures, heparin was neutralized with protamine (0.8 mg of protamine per milligram of heparin). CPB was established with cardiac indices of 2.0 - 2.5 $L.min^{-1}$ m^{-2}. Cooling was stopped at 33° C in patients operated on without the cross-clamp technique under mild hypothermia. Arterial inflow adequacy was assessed clinically.

Acid-base management during mild hypothermia was via an alpha-stat approach. Before opening the left atrium, the head-down position (Trendelenberg) was established and immediately after opening the left atrium, provision was made to render the mitral valve incompetent so that the left ventricle would pump into the left atrium instead of the aortic root.

The postoperative hemostasis protocol used was derived from that proposed by Szefner[6] and included tests for platelet function, thrombin formation and its regulatory pathways, and for the fibrinolytic system. Treatment included the administration of small doses of protamine, modulated doses of aprotinin, fresh frozen plasma as well as fibrinogen. Dosages were adapted to each patient's clinical profile as well as to test interpretation criteria in order to provide personalized treatment.

Statistical Methods

Medical records of all the 52 patients operated on for malfunctioning mitral valve between July 18, 2000, and June 20, 2002, were reviewed and preoperative variables that were believed to have an impact on outcome were obtained (Table I). Data were studied by descriptive and statistical analyses. SPSS application software version 10.0 (SPSS Inc., Chicago, Ill.) was used for statistical analyses.

Significant differences between the two procedure groups (i.e., median sternotomy and right thoracotomy without aortic cross-clamping) were assessed with univariate analysis (Table I to III):

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categoric data were compared by means of the X^2 test or the Fisher exact test (as appropriate) and continuous variables with the student t test. Data were further analyzed by univariate and multivariate logistic regression with the response variable on the one hand being hospital mortality (30 days mortality) and on the other hand, morbidity. All variables with a zero or near-zero cell count were treated as continuous so that convergence could be obtained. Multivariate models were applied to isolate the effect of each factor adjusted for all other factors: the 0.25 level ($P \leq 0.25$) was used as a screening criterion for the selection of candidate variables. In order that problems created by multi-colinearity could be avoided, variables that were too highly correlated among themselves were included at different times in different models. A background procedure was used. A Wald X^2 test was used for testing the significance of individual coefficients. The results are shown as odds ratios with 95% confidence intervals.

Results

Descriptive Analysis

Mortality: Overall hospital mortality was 14% (8 patients, Table III).

Table III. Complications

	Right Thoracotomy (n=7) Without X clamp	Median Sternotomy (n=45) C X clamp
Hospital mortality (30 days)	1(14%)	9 (20%)
No complications	0	32(71%)
One or more complications	3 (43%)	40 (89%)
Intra operative death	0	4(9%)
Reoperation	0	3(7%)
Prolonged inotropic support	2 (28%)	12 (27%)
Intra operative death	0	4(9%)
Post operative death (30 days)	1 (14%)	7(15%)
Multi organ failure/ sepsis (death)	1 (14%)	3 (7%)
Death	0	2(4%)
Permanent stroke	0	3 (7%)
Hemodialysis	0	2 (4%)
Prolonged respiratory support	1 (14%)	14 (31%)

Intraoperative mortality was 7% (4 patients). Intraoperative deaths included all 4 patients with bleeding from coagulation disorders. The bleeding was due to the poor quality of the ventricular tissue at the site of adhesion release in 2 patients and to the technique of repair in the other patients.

Mortality from cardiac causes was 9% (4 patients); 3 patients could not be weaned from CPB because of intractable cardiac dysfunction and 2 died postoperatively of low cardiac output on postoperative days 8 and 15, respectively. Permanent neurologic damage with cerebral death occurred in 2(4%) patients. Sepsis, complicated by multiorgan system failure (specifically renal and respiratory failure), was the cause of death in 3(7%) patients. Multiple reoperation for bleeding were required in 3 other patients. Intravascular disseminated coagulation in its different phases was present in all the patients from the time of admission. Despite aggressive management and routine blood coagulation tests, coagulation factor levels and fibrinolysin remained abnormal for the duration of CPB and at varying degrees after discontinuation of CPB. Factor V, factor VIII, fibrin degradation products, antithrombin III. D- dimer levels, and platelet counts were the most evident defects before, during, and after CPB and in the postoperative period.

Prolonged postoperative inotropic support for low cardiac output was required in 14 patients. Respiratory failure necessitating tracheostomy for prolonged assisted ventilation occurred in 4 patients, of whom 2 died of sepsis before hospital discharge. Stroke with neurologic damage complicated the postoperative course of 3 patients.

Two patients required hemodialysis treatment. The presence of renal failure in the postoperative period was associated with death in all the patients with this complication.

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The mean duration of hospital stay was 37 days with an average of 9 days in ICU.

Late mortality

Two patients who had preoperative moderate COPD required prolonged ventilatory weaning and were discharged from ICU after 32 and 44 days respectively. Of these, 1 died of pneumonia 3 months after the operation and the other died of ventricular arrhythmia during re-hospitalization for respiratory failure. One patient who had postoperative renal failure died of cardiac arrest during dialysis 5 months after the operation.

Statistical analysis

The two procedure groups examined (right thoracotomy vs. median sternotomy) were not significantly different from each other with respect to the majority of perioperative characteristics that are believed to have an impact on outcome in patients with malfunctioning prosthetic mitral valve (table I and II). As indicated by univariate analysis, perioperative patient variables correlated to operative mortality were median sternotomy (p<0.001), bleeding (p<0.001), and cardiac ischemia (p=0.02). For morbidity, univariate analysis indicated the following significant variables: median sternotomy (p<0.0001), and preoperative myocardial ischemia (p= 0.05). Mortality and morbidity models based on multivariate logistic regression analysis confirmed that median sternotomy (as a continuous variable) is by far the most important risk variable.

Discussion

In recent years, technical improvement in emergency redo mitral valve operations for mal-functioning prosthetic mitral valves, associated with better perioperative management and postoperative care of the patient, have resulted in an acceptable decline in hospital mortality rate.

In our hospital, the results obtained in right thoracotomy incision without cross – clamping of the aorta (table I to III) confirm these achievements. The dismal outcome that we have observed in patients with median sternotomy with the cross – clamping of the aorta indicates that the procedure and the consequent cross – clamping of the aorta further exposes this population to the risk of complicated outcomes. Median sternotomy patients have higher hospital mortality and more complications, even though preoperative differences between the two procedural groups are trivial. This is particularly the case for the variable found to be critical in the statistical model of mortality and morbidity elaborated in this study. The same models indicate that many perioperative factors traditionally associated with a poor outcome, such as renal insufficiency, stroke, cardiac insufficiency and chronic obstructive pulmonary disease, do not serve here as predictors of mortality and morbidity, thus confirming the advances made in the management of patients with acute malfunctioning mitral valve. The critical influence of median sternotomy as the most important variable on the postoperative outcome is demonstrated by our study.

From a statistical point of view, the variable "redo median sternotomy with cross-clamping of aorta" condenses a variety of factors that are very difficult to categorize and quantify. These include physiologic and pathologic factors related to the normal degenerative processes of tissues that are beyond the control of the surgeon. As such, significant reductions in mortality rates appear very difficult to achieve. Our study corroborates the hypothesis that median sternotomy with the cross–clamping of the aorta goes beyond the limits of surgery in very ill patients, unlike other cardiac operations,

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which can be performed via right thoractomy without arresting the heart with a high risk but with a favorable long-term outcome.

In this era of diminishing economic resources for health care, the question of whether such a new approach of surgical therapy should be offered to these patients is very relevant.

Society must always face the reality of limited medical resources and must find mechanisms for distributing these resources fairly and efficiently. In recent years the focus for the evaluation of health services has shifted from unnecessary treatment, especially unnecessary surgery, to the appropriateness of the treatment. Treatments that are extremely unlikely to be beneficial and are extremely costly may be considered inappropriate and hence inadvisable, but they should not be labeled futile. Three sources of value are defined that give meaning to "appropriateness" in patient care: the clinical point of view, the point of view of each individual patient, and the societal point of view[4]. These concepts necessitate that the ethical and economic implications of medical services be integrated into outcome – based guidelines.

The aim of this study was to examine whether surgery for redo mitral valve malfunction in critically ill patients via median strenotomy and arresting the heart is beneficial to this population. In light of the data presented, we conclude that such surgical treatment is inappropriate while right thoracotomy without cross – clamping the aorta remains our other option. In all these cases the surgeon is emotionally and ethically involved. As stated by Daniel J. Ullyot[5] the appropriate application of technology begins early in the clinical encounter. Very often, in the presence of very ill subjects, what appears as inappropriate is to refer the patient for surgery. A surgical consultation offers the patient more than the simple agreement to do the procedure, because it creates expectations in the patient or patient's family, making the decision how to operate extremely difficult. So that these difficulties can be overcome, practice guidelines based on scientific data need to be written. The present work aims to provide a small contribution to this commitment.

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