**Early Morbidity and Mortality after Mitral Valve Replacement with Mechanical Valve**

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**ABSTRACT:**

**Background:**Mitral valve replacement surgery has substantially progressed along the last few decades. Only few reports from Upper Egypt cardiac surgery centers are currently available.

**Aim:**The aim of this study was to evaluate early morbidity and mortality in patients who had mitral valve replacement with mechanical valve prosthesis in Sohag University Hospital.

**Methods:** Two hundred and forty eight consecutive adult patients who had mitral valve replacement with mechanical prosthetic valve at Sohag University Hospital between March 2006 to June 2011 were included in the study. All patients were operated by single team of cardiac surgeons and anesthesiologists and followed up regularly for at least three months postoperatively. Data were extracted from prospectively collected database. Morbidity and mortality were reported according to internationally standardized guidelines.

**Results:** The predominant lesions were mitral stenosis in 104, regurgitation in 50 and mixed in 94 patients (42%, 20% and 38%, respectively). Atrial fibrillation (AF),left atrial thrombus and history of cerebrovascular stroke were reported166, 88 19 patients, respectively (66.8%, 35.5%, 7.6%, respectively). Mitral valve pathology was rheumatic in 221, degenerative in 8, endocarditis in 10 and prosthetic valve dysfunction in 9 patients (89.1%, 3.2%, 4.0% and 3.6% respectively). NYHA (New York Heart Association) class III predominated (56.9%). Mitral valve replacement was carried out in all patients and with concomitant tricuspid annuloplasty in 72 patients (29%). Early mortality occurred in 24 patients (9.7%). Early morbidity due to non-thromboembolic events was related mainly to pulmonary complications, Sternal wound infection and mediastinal bleeding. A variety of thromboembolic complications including cerebral, retinal peripheral vascular insults occurred in 23 patients (9.3%)and led to residual deficits neurologic and visual field defects.

**Conclusion:**Mitral valve replacement with mechanical valve is the treatment of choice for many significant mitral valve lesions. Although life saving, it carries the risk of several complications that can be avoided by optimizing pre, intra and postoperative management.

**Keywords:** valve replacement, thrombosis, endocarditis, anticoagulants.

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**INTRODUCTION**:

Since its introduction during the early sixties, valve replacement has significantly improved the clinical outcome of patients with valvular heart disease.1For most significant heart valve lesions; surgical therapy remains the treatment of choice that provided long lasting relief of symptoms.2

 An ideal valve substitute should resemble the normal native valve characteristics. Principally, it should have superior hemodynamics, long durability, high thrombo-resistance and excellent implantability1.Despite the remarkable progress in prosthetic valve design and surgical procedures over the past decades; valve replacement has not provided a definitive cure.1Two options exist for native valve replacement; mechanical and bioprosthetic valves.3Mechanical valves are preferred for individuals under age of 65 years due to their improved durability and longevity.4

**PATIENTS AND METHODS:**

**Study design, data collection:**

Medical records of all patients who had valve replacement surgery at a single tertiary medical center (Sohag University Hospital) between March 2006 and June 2011 were initially reviewed. Among this population, two hundred and forty eight consecutive adult patients who underwent mitral valve replacement by single team of cardiac surgeons and anesthesiologists were retrospectively enrolled in the study. Exclusion criteria comprised pediatric population, aortic or double valve replacement, associated CABG or missing scheduled follow-up visits during the first postoperative three months. Early morbidity and mortality were reported according to internationally standardized guidelines.5The study protocol was approved by the Local Ethics Committee. An informed consent was obtained from every patient prior to surgery.

**Operative technique:**

 Median sternotomy and standard cardiopulmonary bypass with aortic and bicaval venous cannulation was carried out for all patients. Moderate hypothermia (28-32ºC) and intermittent perfusions of cold blood cardioplegia in an antegrade cannula were used for myocardial protection. Posterior mitral valve apparatus preservation was our preferred technique and the anti anatomical position was chosen for valve implantation. Types of implanted valves were carbomedics (Sulzer Carbomedics , Austin, TX, USA), St Jude (St Jude medical, MN, USA) and Sorin (Sorin Biomedical Cardio, Sollogia, Italy).

**Postoperative care:**

Anticoagulation was commenced on day one postoperatively using a combination of low molecular weight heparin and warfarin provided that there was no evidence of active bleeding. Patients were maintained in hospital until a therapeutic INR (2.5-3.5) was achieved. Patients had echocardiographic examination just before discharge as control for subsequent visits.

**Follow-up**:

Patients were discharged from our department with a follow-up card including instructions about anticoagulant therapy and prophylaxis against endocarditis. Follow up visits were scheduled weekly during the first month, twice monthly during the subsequent 5 months and once monthly thereafter.

**Statistical analysis:**

Statistical analysis was performed with SPSS software ver. 19 (SPSS Inc, Chicago, IL, USA) and Microsoft Office Excel 2007. Descriptive statistics are reported as mean ± standard deviation for continuous variables and as percentages for categorical variables.

**RESULTS:**

**Demographic, Clinical and Preoperative data and Surgical interventions:**

 A total of 248 consecutive patients (157 (63.3%) females and 91(36.7%) males) with mitral valve disease who met the inclusion criteria were enrolled. Their mean age was 33±10 (range: 16-67) years. Mitral stenosis was diagnosed in 104, mitral regurgitation in 50 and mixed lesion in 94 patients (42%, 20% and 38%, respectively). Demographic data, NYHA classification, rhythm status and comorbodites were summarized in Table 1.

**Table (1): Demographic, Clinical and Preoperative data of patients**

|  |  |  |
| --- | --- | --- |
|  |  (n=248) | % |
| Age | 33±10 |  |
| Gender  |  |  |
| Male  | 91 | 36.7% |
| Female | 157 | 63.3% |
| NYHA classIIIIIIV | 8414123 | 33.9%56.9%9.2% |
| Rhythm  |  |  |
| Sinus | 82 | 33.1% |
| AF | 166 | 66.9 % |
| Comorbidities |  |
| Hypertension  | 45 | 18.1% |
| Diabetes mellitus | 65 | 26.5% |
| Cerebrovascular disease | 19 | 7.7% |
| Hepatic dysfunction | 4 | 1.6% |
| Chronic lung disease | 5 | 2% |

 Preoperative clinical and echocardiographic evaluation is shown in Table 2. Mitral valve pathologic lesions entailed rheumatic affection in 221, degenerative disease in 8, remote endocarditis in 10 and prosthetic valve dysfunction in 9 patients (89.1%, 3.2%, 4.0% and 3.6%, respectively). Left atrial thrombus was detected preoperatively by echocardiography in 88 cases (35.5%), among them 16 (6.5%) disclosed history of embolic manifestations. Thirteen patients (5.2) were previously subjected to closed mitral commissurotomy while 9 patients (3.6%) had balloon mitral valvotomy.

**Table (2): Preoperative Clinical and Echocardiographic Cardiac Evaluation**

|  |  |  |
| --- | --- | --- |
| Finding | no | % |
| Endocarditis | 12 | 4.8% |
| Previous mitral intervention(s) | 24 | 9.7% |
| Left atrial thrombus | 88 | 35.5% |
| Prosthetic valve dysfunction | 9 | 3.6% |
| Ejection fraction |  |
| ≥ 6o | 42 | 17.0% |
| 40-59 | 171 | 69.0% |
| 20-39 | 35 | 14.0% |
| \*PASP ( mean±SD) | 47.3±9.4 |

**\***PASP: Pulmonary Artery Systolic Pressure

 The most common sizes of the implanted valves were 29 and 31 (36% and 31% respectively, Figure1). Nine patients (3.6%) were operated as emergency while the rest (96.4%) underwent elective surgery. Tricuspid valve annuloplasty (DeVegaʼs)6 was simultaneously performed in 72 patients (29.0%) for moderate or severe organic tricuspid regurgitation. Implanted valves were 64 (25.8%) carbomedics (Carbomedics, Austin, TEX, USA), 95 (38.3%) St Jude (St Jude medical, IN, USA) and 89 (35.9%) Sorin (Sorin Biomedical Cardio Sollogia,Italy).



**Figure (1) Percentage of implanted valve sizes**

**Early mortality:**

Total early mortality was 9.7% (24 patients) including intra and postoperative mortality. Intraoperative mortality occurred in 3 cases during reoperations for prosthetic valve dysfunction (1.2%) during which uncontrolled bleeding occurred most likely due to prolonged cardiopulmonary bypass and extensive adhesolysis. Another 3 cases (1.2%) had pump failure with (preoperative EF<40%). Postoperative death, which was related to several factors (Table 4), occurred in 16 patients.

**Table(4): Causes of Postoperative Mortality**

|  |  |  |
| --- | --- | --- |
| Cause of death | No | % |
| Low cardiac output  | 2 | 0.8% |
| Cerebrovascular stroke | 3 | 1.2% |
| Uncontrolled sepsis | 2 | 0.8% |
| Cardiac tamponade | 1 | 0.4% |
| Bleeding | 2 | 0.8% |
| Respiratory failure | 2 | 0.8% |
| Renal failure | 1 | 0.4% |
| VF | 2 | 0.8% |
| Endocarditis | 1 | 0.4% |
| Total | 16 | 6.45% |

 **\***VF: Ventricular Fibrillation

**Early morbidity:**

Early morbidity was related to non thromboembolic (Table 5) and thromboembolic events as summarized in (Table 6).

  Mediastinal bleeding occurred in10 patients (4%) and was controlled by reexploration in 8 patients (3.2%) and conservative measures in 2 patients (0.8%). Five patients (2%) had postoperative cardiac tamponade, which was successfully managed by reexploration in 4 patients (1.6%). A number of pulmonary complications including pneumonia (6 patients, 2.4%), atelectasis (10 patients, 4%), pneumothorax (6 patients, 2.4%) and pleural effusion (24 (9.6%) patients (6 bilateral, 14 left and 4 right side) were reported. Fourteen patients (5.6) suffered from sternal wound infection. Lines of treatment entailed systemic antibiotics according to culture and sensitivity (10 patients, 4%), multiple surgical debridement and reconstruction (4 patients, 1.6%). Sepsis developed and led to death in 2 patients. Two patients (0.8%) developed transient postoperative jaundice, which responded to medical treatment. Renal impairment complicated the postoperative course and necessitated renal dialysis in two patients (0.8%), only one of them survived.

**Table (5): Non-Thromboembolic Events**

|  |  |  |  |
| --- | --- | --- | --- |
| Event | No(%) |  |  |
|  |  | **Management** | **Deaths (n=7)** | **Remarks** |
|  |  | **Reoperation Conservative** | No (%) |  |
| Mediastinal bleeding | 10(4%) | 8(3.2%) | 2(0.8%) | 2 (0.8%) |  |
| Cardiac tamponade | 5(2%) | 5(2%)  | 0 | 1(0.4%) | MV |
| Pulmonary complications |  |  |  |  |  |
| PneumoniaAtelectasisPneumothoraxPleural effusion |  6 (2.4%)10(4%)6 (2.4%)24(9.7%) | 006\* (2.4%)10\* (4%) | 6(2.4%)10(4%)014 (5.6%) | 1(0.4%)000 | MV |
| Sternal infection | 14(5.6%) | 4(1.6%) | 10(4%) | 2(0.8%) |  |
| Jaundice | 2(0.8%) | 0 | 2(0.8%) | 0 |  |
| Renal impairment | 2(0.8%) | 0 | 1(0.4%) | 1(0.8%) | MV |

**\***ICTD:Intercostal tube drainage, MV:mechanical ventilation

Thirty-seven patients (14.9%) suffered from postoperative arrhythmia. Recent AF was the predominant form (occurred in 31 patients, 12.5%), among them 10 (4%) could be converted to sinus rhythm after medical and DC cardioversion, while the remaining 21patients (8.5%) were discharged with AF after rate control. Ventricular fibrillation was reported in 4 patients (1.6%), who also received DC cardioversion. Two patients (0.8%) returned to sinus rhythm, while the other two patients died after failed trials of DC cardioversion.Three patients (1.2%) had transient post-operative atrioventricular (AV) block, which required temporary pacemaker. All returned to sinus rhythm during the second postoperative day.

 Transient ischemic attack (TIA) was diagnosed and adequately managed by thrombolytic therapy in 12 patients (4.8%). Eight patients (3.2%) developed neurological deficit (monoparesis, hemiparesis or hemiplegia), which led to death of 3 patients. Central retinal artery thrombosis occurred in one patient and led to residual visual field defect. Non-cerebral embolic events occurred in 2 patients (0.8%) including right external iliac artery thrombus in one patient and right femoral artery embolus in the other. Both patients survived and their limbs saved after appropriate surgical intervention.

**Table (6):Thromboembolic Events**

|  |  |
| --- | --- |
| No (%) | Event |
| 12 (4.8%) | TIA | Cerebral n=21(8.5%) |
| 8 (3.2%) | Stroke |
| 1 (0.4%) | CRAO |
| 1 (0.4%)1 (0.4%) | Right external iliac arteryRight femoral artery | Non cerebral n=2(0.8%) |

\*CRAO: Central retinal Artery Occlusion

 Valve related complications included; prosthetic valve endocarditis in one patient (0.4%) and valve thrombosis (0.4%) in another. Both developed during the second month after discharge and were managed with aggressive antibiotics and anticoagulation. No reported cases of malfunctioning valve in our series in the early follow up period.

**DISCUSSION:**

Upper Egypt medical centers have published a few studies on their experience in mitral valve surgery. In this report, we presented a retrospective study on a single tertiary medical center (Sohag University Hospital) experience with early morbidity and mortality after mitral valve replacement surgery. The study was carried out on a relatively large number of consecutive adult patients who were operated by single surgery-anesthesiology team. To ensure accurate evaluation, we adhered to internationally recognized guidelines on defining morbidity and mortality.

 There has been a choice of mechanical prosthesis and bioprosthesis as valvular substitutes for cardiac valve replacement surgery for many years.7The ideal valve prosthesis as described by Harken8should have durability, longevity and no thrombogenicity like native valve. It should have no inherent gradient in and of itself and would allow for unimpeded outflow. Furthermore, it should be easily implanted and readily available. Finally growth commensurate with that of the recipient would be possible.8

 Most of the available prosthetic heart valves function remarkably well9; nonetheless they are associated with complications that significantly influence their clinical use. It has been reported that about 60% of patients with substituted valves develop a serious prosthesis-related complications within 10 years postoperatively10. Mechanical valves have excellent durability with substantial risk of thromboemboli and thrombotic obstruction and therefore require long-term anticoagulation, which is associated with increased risks of hemorrhagic complications1.

 This study included 248 patients with median age of 24 (range: 16-67) years. Obviously contrasting our study, previously published population-based studies (STS National Database: 13936 patients who had isolated mitral valve replacement) showed that the median patients’ age was 58 years11.However; this may be explained by that most of our patients (89.1%) suffered from rheumatic valve lesions that affect younger age groups.

 Class III was the predominant (56.9%) NYHA class among patients followed by class II and IV.This accords with Ruel et al12 who found that the majority of cases were in class III (49.5%) followed by class IV, I and II, respectively. In the same line with Bando et al11, which showed that AF was diagnosed in 78% of patients, the incidence of AF among our patients was 68.6%.

 Several comorbidities such as hypertension, chronic lung disease, diabetes mellitus, cerebrovascular disease and renal failure were noted in our patients. Gammie et al13showed increased incidence of hypertension (57.1% versus 18%) chronic lung disease (22.4% versus 2%), but less diabetes (14.4% versus 26%) compared with our study.

 In this study, early mortality occurred in 8.8% of cases which is almost similar to Hellgren et al14(9.0% for MVR) and only slightly higher than the STS National Database and the CSCR population-based studies (6.0 and 6.2%, respectively). 7,15

 The main causes of the postoperative mortality in our study population were cerebrovascular stroke (1.2%), uncontrolled sepsis (0.8%), low cardiac output (0.8%) and ventricular fibrillation(0.8%). Hellgren et al14showed slightly higher incidence of cerebrovascular stroke and sepsis as a cause of early mortality (3.6% and 2.9%, respectively). In our series, only 2 patients (0.8%) died because of low cardiac output which was almost similar to Jamieson et al7(0.6%) and lower than Remadi et al (1.5%).16Similar to our findings, prosthetic valve endocarditis was not implicated in postoperative death in their study.7,13

Reoperations have higher morbidity compared with the first operation owing to presence of cardio-pericardial adhesions that carry the risk of cardiac injury and fatal hemorrhage. In reoperated patients more advanced cardiac pathology is frequently found and consequently leads to increased operative and postoperative morbidity and mortality.17In this study, 8 patients died among a total of 24 (33.3%) who had reoperations (death occurred intraoperatively in 3 patients and postoperatively in 5 (mediasinal bleeding, cardiac tamponade and sternal infection).

 Jamieson et al7 did not report prosthetic valve endocarditis as a cause of postoperative death in his study while we reported one case (0.4%), of early mortality after prosthetic valve endocarditis.

 Excessive bleeding postoperatively represents an important complication following open-heart surgery. Resternotomy for bleeding results in longer ICU stay and increases the transfusion-related risks.18For instance, severe postoperative bleeding was previously reported to be 10%.14In our study, bleeding occurred in 15 cases (6%), among them 5 were presented with cardiac tamponade. Thirteen patients had resternotomy with three cases of death (1.2% of total group).

 Patients who undergo heart valve surgery via median sternotomy with cardiopulmonary bypass often experience pulmonary complications postoperatively.19 Frequency of those complications varies widely among different studies. 20 In the current study, postoperative pulmonary complications included pneumonia (6 patients, 2.4%), atelectasis (10 patients, 4%), pneumothorax (6 patients, 2.4%) and pleural effusion (24 patients, 9.6%). Apart from one patient who died from respiratory failure, conservative management was successful in the remaining patients.

 Acute kidney injury (AKI) takes place in up to 40% of patients after cardiac surgery, requires dialysis in 1% with higher risk of mortality and morbidity and longer hospitalization.17In STS study (1.4%) developed AKI.21 In this study, two patients (0.8%) developed acute kidney injury. One recovered after 3sessions of dialysis while the other died.

 Of note, thromboembolic events could result in catastrophic outcome after mitral valve replacement surgery. A total of 23 patients (9.3%) developed thromboembolic complications. No deaths were recorded in patients with non-cerebral events. Among patients who had cerebral events, all those who suffered from TIA survived without residual neurologic impairment. Mortality occurred in the subgroup of patients who developed neurologic deficits despite aggressive thrombolysis. Our results contradict several published studies which showed that thromboembolism represents a minor problem after mitral valve replacement surgery since the number of patients who suffered from this entity is almost negligible (from 0% to 2.2%).22 From these results, it is obvious that our patients exhibited remarkable rise in thromboembolic complications in comparison with the Western studies. This could be explained, at least partially, by the inadequate compliance from a number of our patients even with the thorough follow up that our team has provided. However, this problem could be easily overcome by provision of adequate system for anticoagulation management23 that is likely to improve our patient compliance.

 Most of the patients in subgroup of combined mitral replacement and tricuspid annuloplasty (44 out of 71) were operated during the last two years of the study. In essence, increased prevalence of moderate to severe tricuspid regurgitation and availability of intraoperative trans-esophageal echocardiography (TEE) might have contributed to the recent increase in the number of concomitant mitral-tricuspid surgery. 24

 There were several points that strengthened the results of our study such as inclusion of a large number of consecutive patients, interventions by the same surgery-anethesiology teams in a single tertiary care medical center. However, it should be emphasized that several inherent defects of the retrospective studies could not be avoided such as missing certain data and inadequate statistical analysis. Therefore, further prospective studies are warranted for precise assessment of postoperative complications after mitral valve replacement surgery.

**Conclusion**

 In conclusion, we showed that the rates of early postoperative complications after mitral valve replacement surgery are comparable with previously published studies.

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**الاعتلالات والوفيات المبكرة بعد جراحة استبدال الصمام الميترالي بصمام صناعى ميكانيكى**

**مقدمة:** لقد شهدت جراحة استبدال الصمام الميترالي تقدما كبيرا فى العقود القليلة الماضية. تتوفر حاليا قليل من التقارير حول نتائجها من مراكز جراحة القلب بجنوب مصر.

 كان الهدف من هذه الدراسة تقييم الاعتلالات والوفيات المبكرة للمرضى الذين أجرى لهم استبدال الصمام الميترالى بصمام صناعى ميكانيكى وذلك بمستشفى سوهاج الجامعى.

**طرق البحث:** اشتملت الدراسة على 248 مريضا أجريت لهم جراحة قلب مفتوح لاستبدال الصمام الميترالى بصمام صناعى ميكانيكى ثنائى الشرفات وذلك فى الفترة من مارس 2006م حتى يونيو 2011م في مستشفى سوهاج الجامعى وقد قام بإجراء الجراحة فريق جراحى واحد وكذلك فريق واحد من أطباء التخدير وتمت دراسة بيانات التسجيل للمرضى من قواعد البيانات بالمستشفى وتم رصد الاعتلالات والوفيات وتسجيلها طبقا للقواعد الاسترشادية العالمية المعتبرة.

**نتائج البحث:** قد مثل ضيق الصمام الميترالى 104 مريض والارتجاع 50 وكلاهما معا 94 مريضا بنسب مئوية بلغت (42٪ و20٪ و38٪) على التوالى. هذا وقد مثلت حالات الارتعاش الأذينى وجلطات الأذين الأيسر والجلطات الدماغية حوالى (66,8٪ و35,5٪ و7,6٪) على التوالى.وقد كانت الإصابات فى الصمام ناتجة عن حمى روماتيزمية فى221 مريض ونتيجة للتنكس فى ثمان مرضى والتهاب الشغاف المبطن للقلب فى 10 مرضى وكانت حالات الخلل فى عمل صمام ميكانيكى سبق وضعه فى 9 مرضى وذلك بنسب (89,1٪ و3,2٪ و4٪ و3,6 ٪) على التوالى.وقد غلبت الدرجة الثالثة فى التصنيف الوظيفى للجمعية الأمريكية لأمراض القلب على عدد الحالات (56,9٪) وقد أجرى استبدال للصمام الميترالى فى جميع المرضى وصاحب ذلك عمل رأب للصمام ثلاثى الشرفات فى 72 مريض ( 29٪) من إجمالى عدد الحالات.

وقد تم حصر حالات الوفيات المبكرة التى حدثت أثناء وبعد الجراحة وكانت (24 حاله بمعدل 9,7٪) ,كان النزيف أثناء وبعد الجراحة سببا رئيسيا للوفيات وكانت الجلطة الدماغية أحد أسباب الوفيات والاعتلالات. كما ساهم فشل الوظائف التنفسية والكلوية فى حدوث بعض الوفيات.

وقد أدى حدوث مضاعفات بالجهاز التنفسى والتهابات صديدية بعظمة القص ونزيف بعد الجراحة بالحيزوم إلى حدوث بعض الاعتلالات بعد الجراحة أدى بعضها إلى حدوث نسبة من الوفيات.

وقد أدى حدوث بعض االخثرات (الجلطات) الدماغية والطرفية إلى بعض المضاعفات المتنوعة فى 23 مريض (9,3٪) أدى بعضها إلى حدوث نسب من العجز الحركى وعيوب فى مجال الإبصار وشفى البعض الآخر.

**الخلاصة**: يعد استبدال الصمام الميترالى بصمام ميكانيكى العلاج الأمثل لكثير من الآفات الهامة التى تصيب الصمام الميترالى وعلى الرغم من كونه منقذا للحياة، فإنه يحمل مخاطر العديد من المضاعفات التي يمكن تجنبها عن طريق ضبط الظروف المناسبة للعلاج قبل، وبعد العملية الجراحية .