Predictors of Outcome of Surgical Management of Prosthetic Mitral Valve Thrombosis or Malfunction

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Background: **Reoperation for prosthetic mechanical valve malfunction became more frequent due to the increasing number of patients replacement of the mitral valve for many pathologies such as degenerative or rheumatic valve disease.**

Method: **Our study included 40 patients with prosthetic mitral valve thrombosis or malfunction, who underwent re-replacement of mitral valve prosthesis (from the first of November 2013 till the end of June 2015) in *Kasr Al-Ainy* University Hospitals.**

Results: **Our patients were 11 males (27.5%) and 29 females (72.5%). The mean age was 35.8 ± 10.1 years. The overall mortality was 7 patients (17.5%). The main risk factors for hospital mortality were preoperative mean arterial blood pressure < 70 mmHg, heart rate > 100 /minutes, acute pulmonary edema, need for preoperative mechanical ventilation, cerebrovascular stroke, disturbed conscious level, preoperative renal dysfunction and low EF. Also, mortality was significantly positively correlated with long cross clamp time, long cardiopulmonary bypass time, need for high inotropic support after weaning from bypass, postoperative mechanical ventilation time, renal failure, stroke, chest infection and wound infection.**

Conclusion: **Low EF, hemodynamic instability, long operative time and renal dysfunction were especially associated with increased mortality. Earlier surgical management before the development of myocardial dysfunction and severe heart failure would improve the results of mitral valve re-replacement.**

Key words: **Mitral prosthesis malfunction - Mitral prosthesis thrombosis - Mitral valve reoperation - Stuck mitral.**

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Reoperation for prosthetic mechanical valve malfunction became more frequent due to the increasing number of replacement of the mitral valve for many pathologies such as degenerative or rheumatic valve disease. Many factors lead to prosthetic mechanical valve malfunction: pannus formation, thrombosis, prosthetic endocarditis and paravlvular leakage. [1]

There have been gradual decrease in perioperative risk for redo valve surgery over the past 20 years, mostly due to better myocardial protection, increased surgical experience and improved patient management. However, mortality rates remain higher than first-time valve replacement surgery. [2]

The aim of this work is to collect, review and analyze the data of patients with prosthetic mitral valve thrombosis or malfunction and evaluate the different variants that can affect the outcome of surgical intervention in these patients.

Material and Methods

This prospective study was conducted in Kasr Al-Ainy University Hospitals, and included 40 patients who were undergoing re-operation for management of prosthetic mitral valve thrombosis or malfunction over 20 months (from the first of November 2013 till the end of June 2015).

We included in our study all patients of both gender at any age who underwent isolated mitral valve re-replacement with or without tricuspid valve repair. Patients with Infective prosthetic endocarditis or with associated cardiac surgical procedure other than prosthetic mitral valve re-replacement were excluded from our study.

Full history was taken from the patients and their relatives with special emphasis on acute onset dyspnea including severity and duration of symptoms and history of embolism. The efficacy of the oral anticoagulation therapy is checked by serial INR level. Full general and local cardiac examination, routine laboratory investigations, ECG, chest X-ray and complete echocardiographic study was done for all patients.

Quantative data was expressed as mean and standard deviation (X±SD), and qualitative data expressed as number and percentage (No. & %). Categorical variables was compared using the Pearson's chi-square test or Fisher's exact test and independent continuous variables was compared by the unpaired Student t test. A P value of less than 0.05* was considered statistically significant, a $P > 0.05$ (non-significant).

Results

This study included 40 patients. They were 11 males (27.5%) and 29 females (72.5%). The age of our patients ranged between 20 - 73 years with a mean of 35.8 ± 10.1 years.

Regarding preoperative congestive heart failure, 11 patients came to the hospital with dyspnea NYHA class III (27.5%), and 29 patients came with dyspnea NYHA class IV (72.5%). Eleven patients reached the hospital with mean arterial blood pressure < 70 mmHg (27.5%). Four patients had acute pulmonary edema on admission and they need preoperative mechanical ventilation (10%).

Regarding associated comorbidities, 5 patients had cerebrovascular stroke (12.5%), 5 patients had renal dysfunction (12.5%), 4 patients had liver dysfunction (10%) and 3 patients had diabetes mellitus (7.5%). Seven female patients were pregnant (17.5%), 3 in the 1st trimester, 3 in the 2nd trimester and 1 in the 3rd trimester.

INR level on admission to the operative room was 1.64 ± 0.75, ranging between 1 – 3.6. Trial of thrombolysis by the cardiologists was done for 1 pregnant patient (2.5%). She was in the 2nd trimester and hemodynamically stable. She went to surgery after failure of thrombolytic treatment and becoming hemodynamically unstable.

Only 3 patients had history of two previous open heart surgery (7.5%). The time passed from the last mitral valve replacement was 63.5 ± 55.8 months, ranging between 5 – 240 months.

The time elapsed to admission to the operating room was ranging from 3 - 72 hours with a mean time 18 ± 22.9 hours. Patients admitted to the operating room urgently (≤ 24 hours) were 33 patients (82.5%), while 7 patients (17.5%) were admitted to the operating room electively (> 24 hours).

Echocardiography of the patients revealed that 5 patients (12.5%) had EF < 50, while 35 patients (87.5%) had EF ≥ 50. Pulmonary artery pressure was ≤ 60mmHg in 23 patients (57.5%), while it was > 60mmHg in 17 patients (42.5%). Regarding echocardiographic assessment of mitral valve prosthesis, elevated pressure gradient was found in 37 patients (92.5%) and paravalvular leak was detected in 3 patients (7.5%).

Intra-operatively, the cause of mitral valve malfunction was thrombus in 29 patients (72.5%), thrombus and pannus in 5 patients (12.5%) and pannus only in 3 patients (7.5%). Six patients needed tricuspid valve repair (15%). During weaning from cardiopulmonary bypass, high inotropic support was required in 14 patients (35%) and low in 26 patients (65%).

Cardiopulmonary bypass time was ranging from 100 – 280 minutes with a mean 129.3 ± 38.8 minutes. Cross clamp time was ranging from 70 - 180 minutes with a mean 89.6 ± 17.6 minutes.

One patient died intra-operatively and 39 patients transferred to the ICU. Another 2 patients died early in the ICU during the first 12 hours. Duration of postoperative mechanical ventilation in the ICU was ranging from 4 – 288 hours with a mean 34.8 ± 56.9 hours.

Six patients needed reexploration due to excessive postoperative bleeding (15.4%). Regarding postoperative complications, 5 patients were complicated with renal failure (13.5%), 3 patients had stroke (8.1%), 7 patients had chest infection (18.9%) and 2 patients had wound infection (5.4%).

The mean of the total ICU stay was 101 ± 74.3 hours, ranging from 40 – 430 hours. The mean of the total hospital stay for discharged patients was 10.6 ± 4.3 days, ranging from 6 - 27 days.

The overall mortality for patients with prosthetic mitral valve thrombosis or malfunction who underwent re-replacement of mitral valve prosthesis was 7 of the 40 patients (17.5%).

On trying to study variables affecting mortality, we found that mortality was significantly correlated with the following preoperative factors **(Table 01)**: mean arterial blood pressure < 70 mmHg, acute pulmonary edema, need for preoperative mechanical ventilation, cerebrovascular stroke, renal dysfunction and low EF.

Also, mortality was significantly positively correlated with long cross clamp time, long cardiopulmonary bypass time and need for high inotropic support after weaning from bypass **(Table 02)**. Regarding the post-operative factors **(Table 03)**, we find that mortality was significantly positively correlated with long postoperative mechanical ventilation time, renal failure, stroke, chest infection and wound infection.

Per-operative Factor	Mortality number	%	P value
• **Age**:			
- Died	38.9 ± 16.3		**0.395**
- Discharged	35.2 ± 8.7		
• **Sex**			
- Female	4/29	13.8%	**0.286**
- Male	3/11	27.3%	
• **NYHA class**:			
- III	0/11	0%	**0.073**
- IV	7/29	24.1%	
• **Mean arterial blood pressure**:			
- < 70 mmHg	4/11	36.4%	**0.047***
- ≥ 70 mmHg	3/29	10.3%	
• **Acute pulmonary edema**:			
- Present:	3/4	75%	**0.013***
- Absent:	4/36	11.1%	
• **Need for mechanical ventilation:**			
- Present:	3/4	75%	**0.013***
- Absent:	4/36	11.1%	
• **Cerebrovascular stroke:**			
- Present:	3/5	60%	**0.03***
- Absent:	4/35	11.4%	
• **Renal dysfunction:**			
- Present:	3/5	60%	**0.03***
- Absent:	4/35	11.4%	
• **Liver dysfunction:**			
- Present:	1/4	25%	**0.552**
- Absent:	6/36	16.7%	
• **Diabetes mellitus:**			
- Present:	1/3	33.3%	**0.448**
- Absent:	6/37	16.2%	
• **Pregnancy:**			
- Present:	2/7	28.6%	**0.355**
- Absent:	5/33	15.2%	
• **INR level:**			
- Died	1.6 ± 0.8		**0.236**
- Discharged	1.9 ± 0.5		
• **Trial of thrombolysis:**			
- Present:	0/1	0%	**0.825**
- Absent:	7/39	17.9%	
• **Previous open heart surgery:**			
- 1	1/3	33.3%	**0.448**
- > 1	6/37	16.2%	
• **Time to admission to the OR :**			
- Died	8.3 ± 6.8		**0.225**
- Discharged	20.1 ± 24.9		
• **EF :**			
- Died	54.9 ± 8.5		**0.015***
- Discharged	62 ± 6.4		
• **SPAP :**			
- Died	72.7 ± 21.5		**0.052**
- Discharged	56.7 ± 18.6		
• **Elevated pressure gradient in the Echo:**			
- Present:	7/37	18.9%	**0.552**
- Absent:	0/3	0%	
• **Paravalvular leak**:			
- Present:	0/3	0%	**0.552**
- Absent:	7/37	18.9%	

Table (1): Preoperative factors associated with mortality:

Intra-operative Factors	Mortality number	%	P value
• **Cross clamp time:**			
- Died	106.43 ± 35		**0.005***
- Discharged	86.1 ± 9.2		
• **Cardiopulmonary bypass time**:			
- Died	180 ± 73.9		**0.001***
- Discharged	118.6 ± 13.1		
• **Thrombus on the prosthetic mitral valve**:			
- Present:	7/34	20.6%	**0.289**
- Absent:	0/6	0%	
• **Pannus on the prosthetic mitral valve**:			
- Present:	1/8	12.5%	**0.569**
- Absent:	6/32	18.8%	
• **Weaning from bypass**:			
- High inotropic support	7/14	50%	**0.001***
- Low inotropic support	0/26	0%	

Table (2): Intra-operative factors associated with mortality:

Post-operative Factors	Mortality number	%	P value
• **Duration of mechanical ventilation****:			
- Died	206.5 ± 102.8		**0.001***
- Discharged	15.1 ± 14		
• **Need for reexploration***:			
- Yes	2/6	33.3%	**0.224**
- No	4/33	12.1%	
• **Renal failure****:			
- Present:	4/5	80%	**0.001***
- Absent:	0/32	0%	
• **Stroke****:			
- Present:	2/3	66.7%	**0.026***
- Absent:	2/34	5.9%	
• **Chest infection****:			
- Present:	3/7	42.9%	**0.016***
- Absent:	1/30	3.3%	
• **Wound infection****:			
- Present:	2/2	100%	**0.009***
- Absent:	2/35	5.7%	

** Intra-operative death = 1 patient*

*** Death intra-operative or early in the ICU = 3 patients*

Table (3): Post-operative factors associated with mortality:

Discussion

Our patients were 11 males (27.5%) and 29 females (72.5%). This sex distribution is similar to many studies like **Ahn et al. (2008)** who studied 20 patients underwent surgical intervention due to mechanical valve thrombosis from January 1981 through March 2006 at Seoul National University Hospital, Korea, 70% of patients were females and 30% were males. Also, **Akay et al (2008)** who studied 62 redo patients underwent mitral valve replacement, between September 1989 and December 2003 in Baskent University Faculty of Medicine, Turkey, 75.8% of his patients were females and 24.1% were males. [2, 3]

Our results differs from a study reported by **AbouelKasem et al. (2007)** who studied 50 patients underwent mitral valve re-replacement for prosthetic mechanical valve dysfunction in the departments of cardio-thoracic surgery, Kasr El-Ainy hospital, Cairo, over the period from February 2004 to March 2007, 28% of patients were females and 72% were males. This big difference is because he excluded pregnant females from his study. [1]

The age of our patients ranged between 20 - 73 years with a mean of 35.8 ± 10.1 years. This is in agreement with many authors in literature as **Fouda et al. (2014)** who studied the outcome of surgical management of 60 patients with mechanical mitral valve dysfunction from July 2011 till June 2013 at Kasr El-Ainy hospitals, Cairo, the mean age was 39 ± 10.14. Also, **Raboi et al. (2010)** who studied 129 patients underwent reoperation for obstructive mechanical valve between January 2003 and April 2007 at Al-Thawrah Hospital, Yemen, the mean age was 34.8 ± 13.4 years. [4, 5]

Our results differs from other communities like a study from Japan by **Matsuyama et al. (2003)** who Studied 92 patients underwent redo mitral valve surgery, between May 1983 and February 2003 at Tenri Hospital, Japan, the mean age was 56.4 ± 10.4 years (range 33 to 74). Also, a study from USA by **Potter et al. (2004)** who studied 106 patients underwent repeated mitral valve replacement between January 1993 and December 2000 at Mayo Clinic, Minnesota, USA, the mean age was 66 ± 12. In a study from UK by **Vohra et al. (2012)** who studied 49 patients underwent redo-MVR between January 2000 and 2010 at Southampton University Hospitals, UK, the mean age was 63 ± 13 years (range 21–80 years). [6, 7, 8]

In Egypt, the most common cause of mitral valve replacement is rheumatic heart disease which is common in young age. While in other communities like USA, UK and Japan, the most common cause of mitral valve replacement is degenerative mitral valve disease which is common in old age. This explains the difference between the age of our patients and the age in these studies.

Many patients reached the hospital with congestive heart failure and this is in agreement with many studies as the study of **Durrleman et al. (2004)** who studied 39 patients presented with prosthetic valve thrombosis and required surgical intervention at Montreal Heart Institute, Canada, he reported that severe congestive heart failure was found in 44% of his patients. Also, **Ahn et al. (2008)** reported that the most frequent clinical presentation was heart failure, presented in 65% of patients. [3, 9]

Regarding NYHA class, our results is concordant with the study of **Ahn et al. (2008)** who mentioned that all patients came with NYHA functional class III or IV at the time of diagnosis. Also, 84% of patients in **AbouelKasem et al. (2007)** study was in NYHA class III and IV. **Brandao et al. (2002)** who studied 146 patients underwent valvular reoperations for prosthetic valve dysfunction between July 1995 and June 1999 at the Heart Institute of the University of Sao Paulo Medical School, Brazil, reported that 91.1% of his patients were in NYHA class III and IV before surgery. [1, 3, 10]

The associated comorbidities were found in all other studies in a similar proportions as ours. **Brandao et al. (2002)** found that 4.8% of his patients with DM, 8.9% with stroke and 9.6% with renal dysfunction. Some studies with older aged patients as, the study of **Potter et al. (2004)** from USA showed a higher rate of comorbidities, 15.1% with DM, 18.9% with stroke and 8.5% with renal insufficiency. [7, 10]

As pregnancy is a risk factor for prosthetic valve thrombosis, many studies show a respectable proportion of pregnant

females, it may reaches 35% of the patients as in **Ahn et al. (2008)** study. **Lafci et al. (2006)** who studied 18 patients presented with PVT (78% had mitral valve thrombosis) between July 1997 and September 2005 at Ataturk Education and Research Hospital, Turkey, reported that 5.6% of patients were pregnant. Also, **Toker et al. (2006)** who studied 63 patients underwent reoperation for obstructive prosthetic valve dysfunction between January 1994 and April 2005 at Kosuyolu Heart and Research Hospital, Istanbul, Turkey, 7.9% of patients were pregnant. [3, 11, 12]

As inadequate anticoagulation and low INR level are risk factors of prosthetic valve thrombosis, many studies reported low INR level of patients. In study of **Ahn et al. (2008)** INR profiles when thrombosis was diagnosed were 1.66±0.64 (1.02-2.68). Also, 72% of **Lafci et al. (2006)** patients had INR < 2. [3, 11]

Bioprosthesis malfunction was in our study scope, but we didn't find any patient with bioprosthesis malfunction during the study period. This is because bioprosthetic mitral valve replacement is not common in our developing countries especially at the governmental hospitals due to its high cost and the patients don't accept unavoidable re-replacement of this valve.

Although, all mechanical prosthetic valves have an excellent record of durability up to 40 years, thrombosis of the mechanical valve may occur at any time even in the 1st week post-MVR. On the other hand, bioprostheses with their limited durability, usually do not fail suddenly, and take time until degeneration, fibrosis and calcification become sufficiently severe to require reoperation.

The time passed from the last mitral valve replacement was 63.5 ± 55.8 months, ranging between 5 – 240 months. And this is concordant with most researches that studied mechanical prosthetic thrombosis, as **Toker et al. (2006)** who found that the mean time to reoperation was 58.9 ± 56.1 months (rang: 1 – 252 months); **Lafci et al. (2006)**, the mean time to reoperation was 48.3 ± 15.4 months; **Durrleman et al. (2004)**, the mean time to reoperation was 39 ± 42 months. [9, 11, 12]

In researches that studied all types of prosthetic mitral valve dysfunction including bioprosthetic mitral valves, the mean time to reoperation is obviously longer. In the study of **Potter et al. (2004)**, 43% of his patients had mechanical mitral valves and 57% had bioprosthetic mitral valves, the mean time to reoperation was 138 ± 85.2 months. [7]

In the study of **Raboi et al. (2010)** the mean time to reoperation was 26 ± 19.2 months (rang: 4 days – 20 years); which is too short in comparison to our study and the other studies. He explained that, by the increased number of valve replacement operations performed at his cardiac center year by year, poverty and lack of adherence of patients to medical instructions especially anticoagulant therapy. [5]

Kasr Al-Ainy University Hospital is considered one of the biggest tertiary center in Egypt with 24 hours available high qualified staff and a large blood bank. Patients usually diagnosed by echocardiography as prosthetic mitral valve thrombosis and referred from other hospitals some times in other governments. They usually reach the hospital with congestive heart failure. So, the patients are prepared for operations in a short period.

In our study, 85% of our patients had mechanical mitral valve thrombosis. The time elapsed to admission to the operating room was short in comparison to other studies of mechanical prosthetic valve thrombosis, as in **Toker et al. (2006)** 65.1% of patients were operated on under emergency conditions. Also, in **Ahn et al. (2008)** 40% of patients underwent an emergency or urgent operations. In **AbouelKasem et al. (2007)** 58% of patients were operated urgently, this is because patients with prosthetic valve thrombosis were 36% only. [1, 3, 12]

Cardiopulmonary bypass time and cross clamp time in our results were similar to the results of **Toker et al. (2006)** who reported that the mean aortic cross clamp time was 85.5±36.4 minutes and total perfusion time was 135.3±68.73 minutes, and **Vohra et al. (2012)** reported that cardiopulmonary bypass time was 120 ± 56 min and cross-clamp time was 92±32 min. [8, 12]

These results were longer than the results of **Durrleman et al. (2004)** who reported that, the cross clamping time was 75 ± 32 minutes (range, 16-133 minutes), and the cardiopulmonary bypass time was 118 ± 48 minutes (range, 31-217 minutes), this is because only thrombectomy was done to 47% of the patients. Our results were shorter than the study of **Matsuyama et al. (2003)** who showed that aortic cross-clamp time was 105 ± 53 minutes and pump time was 185 ± 82 minutes. [6, 9]

We had a higher rate of reexploration in comparison to other studies as **Akay et al (2008)** 7.1%, **Lafci et al. (2006)** 5.6%, **Potter et al. (2004)** 3.8%, **Raboi et al. (2010)** 1.6% and **Vohra et al. (2012)** 4%. [2, 5, 7, 8, 11]

This may be explained by that 82.5% of our patients were operated on under urgent conditions, with a short time to admission to the operative room in comparison to the other studies. There was no time to correct the INR level in some patients, as 10 patient (25%) had INR ≥2.

There were 5 patients (13.5%) complicated with renal failure and needed dialysis. This was similar to the results of **Akay et al (2008)** 14.2%, **Potter et al. (2004)** 10.4% and **Vohra et al. (2012)** 12%. Some studies showed fewer patients was complicated with renal failure as **Toker et al. (2006)** 3.2%. [2, 7, 8, 12]

Total ICU stay was longer in comparison to **Akay et al (2008)** who reported that total ICU stay was 81.6 ± 38.4 hours. Total hospital stay was similar to the results of **Akay et al (2008)** who reported that total hospital stay was 9.1 ± 2.7 days. Our total hospital stay was shorter in comparison to **Ahn et al. (2008)** who reported total hospital stay was 16.9 ± 6.7 days and **Vohra et al. (2012)** who reported 17 ± 11 days. [2, 3, 8]

Our study showed that the overall mortality was 7 of the 40 patients (17.5%). This is similar to the results of **AbouelKasem et al. (2007)** 14%, **Fouda et al. (2014)** 15%, **Lafci et al. (2006)** 16.7%, **Raboi et al. (2010)** 17.8%, **Matsuyama et al. (2003)** 20% and **Toker et al. (2006)** 20.6%. Our mortality rate was higher than other studies as **Ahn et al. (2008)** 5%, **Akay et al (2008)** 6.4%, **Brandao et al. (2002)** 10.9%, **Potter et al. (2004)** 4.7% and **Vohra et al. (2012)** 12%. [1-12]

AbouelKasem et al. (2007) in his study reported that risk factors related to hospital mortality was the presence of pulmonary hypertension more than 60 mmHg, NYHA class of the patients reflecting the pathology of the stuck valve, high creatinine level more than 1.8 mg% and long cardiopulmonary bypass time. **Akay et al (2008)** also reported that low left ventricular ejection fraction (<35%), NYHA functional class IV, pulmonary edema, female gender, and urgent operations were found to be risk factors for mortality. [1, 2]

In the study of **Brandao et al. (2002)** he reported that prolonged extracorporeal circulation time, increased creatinine level, NYHA functional class were associated with higher mortality rates. While, **Toker et al. (2006)** found that the only factor affecting early hospital mortality was left ventricular ejection fraction. [10, 12]

Conclusions

Patients with prosthetic mitral valve thrombosis presenting to Kasr Al-Ainy hospitals are characterized by being young, more commonly females, with heart failure on presentation. Inadequate anticoagulation and low INR level are risk factors of prosthetic mitral valve thrombosis. Pregnant women with mechanical prosthetic heart valves are more vulnerable to prosthetic valve thrombosis. Low EF, hemodynamic instability, long operative time and renal dysfunction were especially associated with increased mortality. Earlier surgical management before the development of myocardial dysfunction and severe heart failure would improve the results of mitral valve re-replacement.

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