

A Prospective Study on Treatment of Prosthetic Valve Thrombosis and its Clinical Presentation

ATIF AHMED KHAN¹, ARSHAD ALI SHAH², SYED DILBAHAR ALI SHAH³, MUHAMMAD ASLAM⁴, SYED AHSAN RAZA⁵

^{1,5}Assistant Professor, National Institute of Cardiovascular Diseases, Karachi

^{2,3}Assistant Professor, Dow University of Health and Sciences/Civil Hospital Karachi

⁴Assistant Professor NICVD Nawab Shah

Corresponding author: Muhammad Aslam, Email: draslamz79@gmail.com, Cell: 0333-3080657

ABSTRACT

Background and Objectives: The thrombosis of prosthetic valve is a lethal complication following replacement surgery of the valve. Few patients report with a thrombotic complication because of poor status of anticoagulation with unbalanced checks of INR. This study was conducted to investigate the clinical profile and treatment of thrombosis of prosthetic valve.

Study Design: A prospective observational study.

Place and Duration: In the Cardiology department of National Institute of Cardiovascular Diseases, Karachi and Nawabshah for one-year duration from January 2021 to December 2021.

Methods: 50 patients with prosthetic valve thrombosis diagnosis were included in this study and analyzed. The clinical parameters, demographic profile and one-year follow-up along with in-hospital outcome were analyzed.

Results: Out of 50 patients; there were 37(74%) females, aged 11 to 67, with 35.5 ± 7.5 years of mean age. 30 subjects (60%) had a subtherapeutic INR value on admission. Atrial fibrillation occurred in 48% of patients on admission. 78% of patients reported in the first week of onset of symptoms, and the main complaint was dyspnoea, which occurred in 90% of patients. Streptokinase thrombolysis was performed in 46 (92%) patients, and surgery was performed in 4 patients. 42 (84%) patients had Mitral valve thrombosis and 8 (16%) patients had isolated aortic valve thrombosis. 14% was the in-hospital mortality, and no new strokes or major bleeding were observed.

Conclusions: Most patients with prosthetic valve thrombosis showed subtherapeutic value of INR and poor patient compliance. Thrombolysis is a beneficial selection for treating patients with thrombosis of prosthetic valve, particularly in Pakistan.

Keywords: Thrombolysis, prosthetic valve thrombosis, subtherapeutic.

INTRODUCTION

A prosthetic valve thrombosis (PV) is a disease condition characterized by formation of thrombus in prosthetic structures and consequent dysfunction of the prosthetic valves with or without thrombosis¹⁻². The thrombosis of prosthetic valve is a serious complication after surgery of the heart valve that ranges from 0.6% to 16% and is related with significant mortality and morbidity. Mortality rates are even higher in developing countries³⁻⁴. Most PVT can happen after months or also years after valve replacement⁵. The thromboembolic event risk and the incidence of thrombosis of PV was greater for mechanical than biological valves, more often in the mitral position than in the aorta, and advanced on the right than on the left side. Prosthetic valve implantation is growing steadily, especially in the Pakistan, as rheumatic heart disease remains common⁶. Most patients have early and late valve replacement complications, especially thrombosis of prosthetic valve and bleeding⁷. Though, many reports around the world about the clinical symptoms and treatment selections for PV thrombosis patients, the ideal management remains provocative⁸. There are various options of treatment be contingent on multiple factors like patient's clinical condition, valve obstruction, the thrombus size, the local economic and medical level, reoperation experience, and most vital is patient selection in our setting⁹. In Pakistan, where the load of cardiovascular diseases, counting rheumatic heart disease, is in height, management and follow-up is difficult after valve replacement, primarily because of inadequate substructure for consistent monitoring of PT / INR profile secondary to financial and geographic restrictions¹⁰⁻¹¹. Patients often have problems like thrombotic events or bleeding, specifically thrombosis of prosthetic valve¹². The primary treatment of PV thrombosis is thrombolytic therapy in our setting primarily for economic issues¹³. The main purpose of this analysis is to investigate the management trends, clinical profile, and short-term treatment outcomes of PV thrombosis.

METHODS

This observational prospective study was held in the cardiology department of National Institute of Cardiovascular Diseases, Karachi and Nawabshah for one-year duration from January 2021

to December 2021. 50 patients with prosthetic valve thrombosis diagnosis were included in this study and analyzed after hospital ethics committee approval. Informed consent was obtained for inclusion in the study and treatment. During the stay in the hospital, the clinical picture, echocardiographic reports, details of the procedure and possible complications were documented. For one-year; all subjects were follow-up. SPSS version 20 was applied for Statistical analysis and the data was accessible in tables. Suitable arithmetical tests were performed for data comparison and a significance level was taken as 0.05. Continuous variables are reported as standard deviation, mean and categorical variables as percentages and numbers. In thrombolysis enduring patients, it was considered successful completely if restore near-normal or normal cross-valve gradients deprived of any grave complications and if successfully partially; means reducing the cross-valve gradient >50% or improving significantly hemodynamically deprived of any grave complications. The thrombolysis failure considered as no significant enhancement in cross-valve gradient and valve function later to treatment, or during thrombolysis, any serious complications occur.

RESULTS

50 subjects with established PV thrombosis diagnosis were admitted during the study period. All subjects were done with clinical analysis and an ECG was executed which was further confirmed by fluoroscopy. There were 37(74%) females, aged 12 to 69, with 35.5 ± 7.5 years of mean age. (Table-1).

Table-1: shows demographic features of patients

Total Patients	45
Gender	
Male	13(26%)
Female	37(74%)
Age	
Maximum	69 years
Minimum	12 years
Mean	35.5 ± 7.5

78% of patients reported in the first week of onset of symptoms, and the main complaint was dyspnoea, which occurred in 90% of patients. It took a long time to develop symptoms from surgery of the valve. The median time of admission was sixty-

months, the first patients admitted 2 months after valve surgery and the last case 144 months later. The majority of patients (90%) reported dyspnoea, and 5 patients reported pain in the chest. Maximum patients (73.3%) were fall in the NYHA class III category followed by NYHA class IV (22.2%). 8 cases (16%) had previous history of thromboembolic events. 31 subjects (62%) had a subtherapeutic INR value on admission, 15 (30%) had an initial INR within the therapeutic range at admission, and 4 patients had a suprathereapeutic value of INR as shownin Table 2.

Table-2: shows patients clinical characteristics

Characteristics	No. (%)
Symptoms	45(90)
Shortness of breath	5(10)
Chest Pain	
NYHA Class	
Class II	2(4.4)
Class III	33(73.3)
Class IV	10(22.2)
Time from onset of symptoms	
<7 days	41(82)
≥7 days	9(18)
ECG (rhythm)	
Sinus	25(50)
Atrial Fibrillation	23(46)
Pacing	2(4)
Past history of Embolic events	8(16)
Hypertension	2(2.2)
Physical examination	
DMC	34(75.6)
DMC with crepitations	11(24.4)
INR Value	
Sub-therapeutic	31(62)
Optimal	15(30)
Supra-therapeutic	4(8)
Complications	
Serum sickness	9(18)
Cardiogenic shock	3(6)
Non fatal Bleeding	3(6)
Mortality	7(14)

Mechanical valve prosthesis St. Jude Bileaflet valve was used in all cases. Streptokinase thrombolysis was performed in 45 (90%) patients, and surgery was performed in 5 patients. Of the patients undergoing thrombolysis, considered successful completely in 38 patients and partial success in 10 patients; however, two patients failed and was then operated on in the same setting. 42 (84%) patients had Mitral valve thrombosis and 8 (16%) patients had isolated aortic valve thrombosis. The mean gradient in a stuck mitral valve prosthesis at presentation varies from 14-31 mmHg, and 22.1 ± 4.9 mmHg of the mean value. The stuck aortic valve mean gradient varies from 42-76 mmHg, with 59.27 ± 10.07 mmHg of mean value (Table 3).

Table-3: shows Gradient across prosthetic valve with PVT

Valve	Maximum	Minimum	Mean
Mitral			
Peak gradient(mmHg)	42.9	20.5	
Mean gradient (mm Hg)	30.8	15.2	22.1 ± 4.9
Aortic			
Peak gradient (mm Hg)	98.4	51.9	
Mean gradient (mm Hg)	75.2	41.5	59.27 ± 10.07

The mean gradient after mitral valve thrombolysis in patients was 8.8 ± 3.2 mmHg; and for aortic prosthetic valve it was 21.5 ± 5.3 mmHg. Mortality was reported in 6 (13.3%) patients, all of whom were treated for thrombolysis in the hospital. Of the patients who died, 4 were completely successful and 2 were partially successful. The communal reason of mortality was refractory heart failure, trailed by cardiogenic shock as given in Tables 4 and 5.

All subjects were followed up for a one-year after discharge. Warfarin was prescribed to all discharged patients, and half of the discharged patients were prescribed aspirin. Details of

pharmacological treatment at discharge from hospital and annual follow-up are presented in Tables 6 and 7, respectively.

Table-4: shows the treatment modalities and its results

Mode of Treatment	No. (%)
Thrombolysis	46(98)
Surgery	4(8)
Thrombolysis Result	
Total	45
Complete Success	38(76)
Partial Success	10(20)
Failure	2(4)

Table-5: shows the causes of mortality among patients

Cause	No.
Refractory Heart failure	4
Cardiogenic Shock	3
Septic shock	2
Total	9

Table-6: shows medication given to the patients on discharge

Medications at discharge	No.(%)
Aspirin	24(48)
Warfarin (Mean Dose 4.7±3.3)	41(82)
Diuretics	42(84)
ACEI/ARB	30(60)
Betablockers	9(18)

Table-7: shows 1-year follow-up of patients

Description	No.
Lost contact	4
Under regular medication n follow-up	34
Recent hospital admission	7
Heart failure	4
Supra-therapeutic INR	1
Total	50

The two groups mortality rate were compared in the studied people. Mortality was comparatively advanced in men under 40, in patients undergoing thrombolysis as a treatment, in patients with partial thrombolysis success, and in patients with MV substitution compared to their peers. Patients with class IV NYHA and an INR >10 had significantly higher mortality, which was statistically demonstrated.

DISCUSSION

50 subjects with PVT, median age 35.5 ± 7.5, were admitted, 74% of whom were women. Several years ago, Hirachan et al also exhibited a comparable prevalence of women and an average age of 37. Though, many intercontinental researches have stated high mean age over fifty-years, but the results of females with a greater predisposition to PV thrombosis were comparable to this analysis. The Indian studies have had a slightly higher incidence among men than women, with an average age under 40¹⁴⁻¹⁵. Numerous analyses have established that PV thrombosis in mitral valve is two-three times common than aortic prosthesis thrombosis, comparable to this study as the mitral valve was most often intricate in the obstacle¹⁶⁻¹⁷. The total mortality in our study was 14% and approximately 16% of the overall mortality in the thrombolysis group which is lesser than in the former study in Lahore; though, the rate was somewhat greater than few intercontinental researches where the rate of mortality was about 7%¹⁸⁻¹⁹. The poor compliance was noted in maximum of the patients in this study, mirrored a lesser baseline INR on admission, as maximum cases (62%) had a subtherapeutic INR. This situation is more communal in emerging states, such as Pakistan, where most people have poor socioeconomic status²⁰⁻²¹. Worldwide, the major causes of PV thrombosis are poor adherence and sub-optimal anticoagulation with sub-therapeutic INR, as has been shown in many studies²². The presence of atrial fibrillation (AF) in

combination with insufficient anticoagulation may play a part in the progression of thrombosis of prosthetic valve²³. 47.1% had AF in this study before, which is parallel to other researches, but in few worldwide studies, the incidence of atrial fibrillation in thrombosis of prosthetic valve was significantly high. Sabahattin et al showed that contingent on the severity of NYHA and surgical emergency, the mortality as high as 70% due to surgery, compared with the stated mortality for TT was 17%²⁴⁻²⁵.

CONCLUSION

The thrombosis of mechanical prosthetic valve is a medical emergency related with augmented mortality and morbidity. The low educational and socioeconomic status of many patients causes poor adherence to oral anti-coagulation treatment and steady follow-up. Even later to thrombosis of prosthetic valve, many patients still did not achieve optimal INR, as more or less 1/4th of patients left without communication during the 1-year follow-up. There are multiple researches on PV thrombosis and the guidelines of treatment are periodically modernized, but in our setting, more emphasis should be placed on preventing such events. For this purpose, appropriate education of the patients should be implemented in order to improve adherence to medical recommendations and regular observations.

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