



## A Study On The Incidence Of Prosthetic Valve Disease And Its Treatment Strategies

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### Abstract

**Introduction:** Prosthetic valve thrombosis (PVT) is a serious and the most dangerous complication, the incidence varies in various parts of the world. The risk factors are multifactorial. The technique of surgical valve replacement introduced in earlier 1960s markedly changed the prognosis of patients having valvular heart disease. Around 300 000 valve replacements are done all over the world each year with both mechanical as well as bio prosthetic valves. In spite of substantial developments in surgical techniques and the design of prosthetic valve over the past decades, replacements of valves have not provided a cure. The durability, hemodynamics and thrombogenicity of the prosthetic valves affect the prognostic outcome of valvular heart disease patients who undergo replacement of valve. Most of the complications related to prosthetic valves can be prevented by optimal selection of prosthesis and its follow up management.

**AIM Of The Study:** To study the treatment strategies of patients presenting with prosthetic valve thrombosis.

**Methodology:** 48 patients who were admitted in the department of cardiology, Department of Cardiology, in the year 2022 at Government Mohan Kumara Mangalam Medical College and Hospital, Salem, Tamil Nadu, India. with signs and symptoms of prosthetic valve thrombosis were included in the study. These patients had prosthetic valve implanted for severe rheumatic heart disease.

**Results:** 48 patients were admitted with signs and symptoms of prosthetic valve thrombosis. Out of which 35 patients were males and 13 were females with the age ranging from 25-48 years. 35 patients (males: 26, females: 9) presented with PVT within one year of implantation and the remaining patients (males: 9, females: 4) presented 1-3years since their valve replacement. On analyzing the previous records, only 28 people were on regular follow up of once in a month and the remaining 20 patients were on less than 2 follow ups after their surgery.

**Conclusion:** Major risk factors for PVT observed in our study are inadequate anticoagulation, lack of follow up and patient prosthesis mismatch. Regarding treatment thrombolysis is a reasonable alternative for surgery with nearly 80% success rate. As the rheumatic heart disease is very much prevalent in India, prosthetic heart valves implantation rate is increasing every year due to high incidence of RHD in India. Inadequate anticoagulation, lack of follow up, non-compliance, lack of health education continues to be the major factors for PVT. Technical and lesion related factors are also important as many cases present early after surgery. So, special care should be taken to avoid patient prosthetic mismatch. Clinical recognition of PVT still plays a vital role, as subtle signs like increase in dyspnea and muffling of clicks may picked up at bedside and leads to suspicion of PVT. Diagnostic tools such as echocardiography (TTE, TEE) play a vital role in diagnosis of PVT through detection of increased gradients and appearance of new regurgitation and visualization of mobility of leaflets.

**Keywords:** Prosthetic heart valve, Streptokinase, Thrombosis, Thrombolysis

## Introduction

Prosthetic valve thrombosis (PVT) is a serious and the most dangerous complication, the incidence varies in various parts of the world. The risk factors are multifactorial. [1]The technique of surgical valve replacement introduced in earlier 1960s markedly changed the prognosis of patients having valvular heart disease. Around 300 000 valve replacements are done all over the world each year with both mechanical as well as bio prosthetic valves. In spite of substantial developments in surgical techniques and the design of prosthetic valve over the past decades, replacements of valves have not provided a cure. [2]The durability, hemodynamics and thrombogenicity of the prosthetic valves affect the prognostic outcome of valvular heart disease patients who undergo replacement of valve. Most of the complications related to prosthetic valves can be prevented by optimal selection of prosthesis and its follow up management.[3] The ideal prosthetic valve should be having the same characteristics of the native valve with good hemodynamics, extensive durability, resistance to thrombosis, and suitable implantability. But, such ideal prosthesis has not been so far found, and the presently available prosthetic valves have many limitations. The treatment strategies such as surgery and fibrinolysis remain the main stay. Trans thoracic echocardiography (TTE), Transesophageal echocardiography (TEE) and sometimes fluoroscopy aids in diagnosis. Prosthetic valve thrombosis is diagnosed when any thrombus, in the absence of infection, adherent over the operated valve or near it, obstructing part of the blood flow or interfering function of the valve.[4]TEE has limitation to distinguish between pannus and infected vegetations from thrombi. In such instances, clinical aspects are helpful. The incidence of PVT is estimated to be 0.1 to 6% per patient-year, of which aortic PVT -0.2% per patient-year, mitral PVT – 1.8% per patient-year.[5] But the incidence should be higher, as TTE and TEE reveals almost all cases and of which half are asymptomatic. Various therapeutic modalities are recommended for PVT. Surgical treatment is

indicated for 69%, according to their NYHA class and emergency situation.[6] Thrombolysis is also recommended as a treatment option, showing more than 80% success and fewer complications. There are no absolute contraindications besides classical contraindications such as early postoperative period large thrombi, pregnancy for thrombolysis. Streptokinase protocols have been used.[7] Heparin can also be a primary treatment option for nonobstructive PVT, but fibrinolysis is more superior. If the size of the thrombi attached to the leaflets is larger, heparin is not helpful. During heparin therapy TEE should be done, as there may be increase in the size of thrombi and can cause obstruction.[8] Thrombolysis, if there are no contraindications can be recommended as first-line of treatment. Surgery is recommended for patients for whom there is contraindication for thrombolysis or where it's deemed to be ineffective. Prosthetic valve thrombosis (PVT) can endanger the life for which therapeutic options remain controversial. It may be salient to review the definitions, tools for diagnosis and their limitations, the epidemiology of PVT before comparing, discussing the different therapeutic modalities that are available for treatment of this condition.[9,10]

## Results

48 patients were admitted with signs and symptoms of prosthetic valve thrombosis. Out of which 35 patients were males and 13 were females with the age ranging from 25-48 years. Overall 38 patients (males: 30, females: 8) were from rural areas and the remaining (males:5, females:5) were from semi urban areas. 30 patients (males: 20, females: 10) had prosthetic valve implanted in mitral position, 17 patients (males: 14, females: 3) had aortic valve prosthesis and one male patient had double valve (both mitral and aortic) replacement. 35 patients (males: 26, females: 9) presented with PVT within one year of implantation and the remaining patients (males: 9, females: 4) presented 1-3years since their valve replacement. On analysing the previous

records, only 28 people were on regular follow up of once in a month and the remaining 20 patients were on less than 2 follow ups after their surgery. Co morbid conditions like dyslipidemia (3 patients), diabetes mellitus (1 patient), and tuberculosis (2 patients) were present. Acenocoumarol was the anticoagulant used for the patients. 38 patients (males: 28, females: 10) were on regular anticoagulant medications. 10 patients were on irregular medications. Various pattern of presentation were noted such as muffled clicks (48 patients), pulmonary edema (36 patients), class IV symptoms (43 patients), new onset off murmur (15 patients), chest pain (24 patients), hypotension (38 patients), atrial fibrillation (12 patients), fever (3 patients) INR <2.5 predisposes to thrombosis. In our study 38 patients had INR <2.5, remaining 10 patients had valve thrombosis despite INR >2.5. Out of 48 patients

34 (70.8%) patients underwent thrombolysis with Streptokinase. 14 (10 mitral and 4 aortic) patients underwent surgery (29.2%). Thrombolysis was successful with return of full leaflet mobility in 22 patients (64.7%). Partial return of leaflet mobility in 7 patients (20.6%). 5 patients died of complications (14.7%). 60% (12/20) of patients had complete success following thrombolysis of mitral valve prosthesis, 77% (10/13) of patients had complete success following thrombolysis in aortic valve prosthesis. One patient with double valve replacement had thrombosis of mitral valve- underwent successful thrombolysis. Total mortality in our study is 7 (14.6%). 3 patients died of fatal bleeding, 2 patients died of Cerebral embolism and 2 patients out of 14 patients who underwent surgery died.

**Table :1 Pattern Of Presentation**

Pattern of presentation	Male	Female
Fever	2	1
Class 4 symptoms	32	11
Chest pain	14	10
Pulmonary oedema	28	8
Hypotension	30	8
New onset murmur	10	5
Atrial fibrillation	2	10
Muffled clicks	35	13

**Table :2 Complications Among Patients**

Complications	Male	Female
Fatal bleeding	2	1
Cerebral embolism	2	0

Figure:1 shows timing of occurrence of valve thrombus following valve implantation

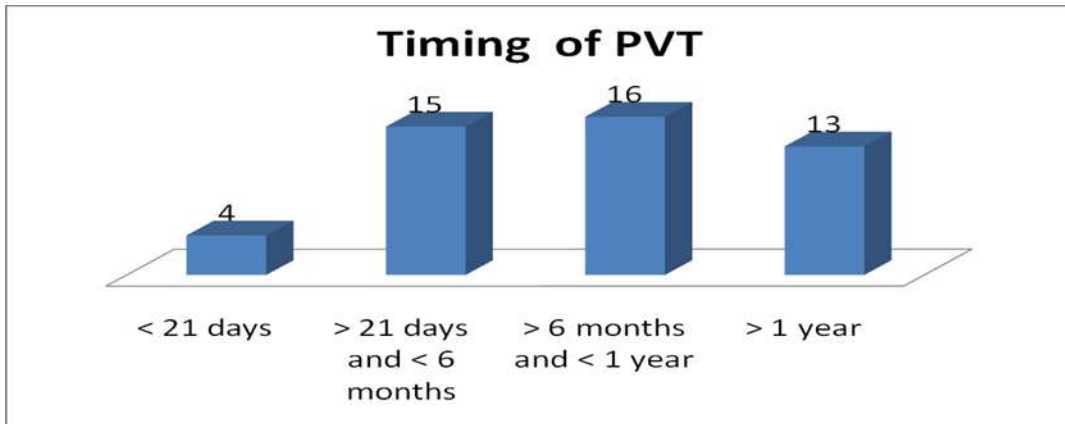


Figure:2 showing follow up course of the patients after valve replacement

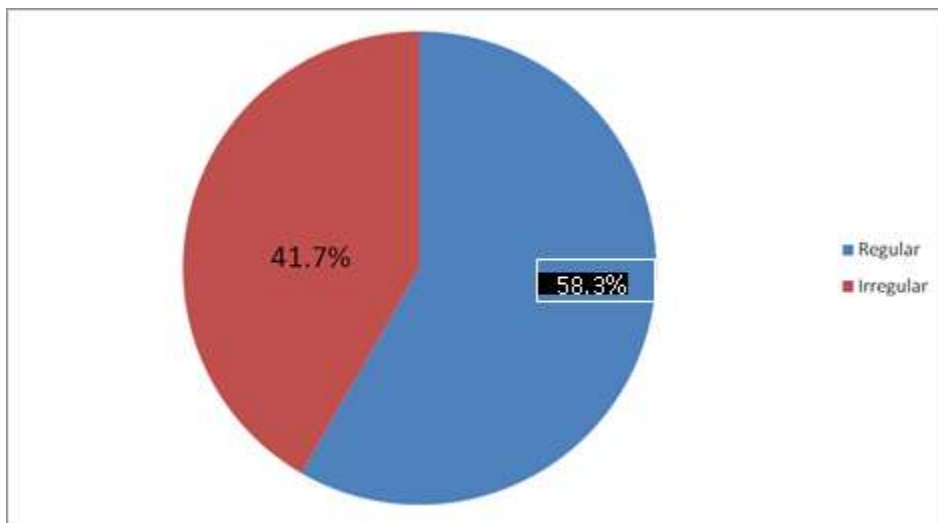


Figure:3 shows level of anticoagulation in the patients

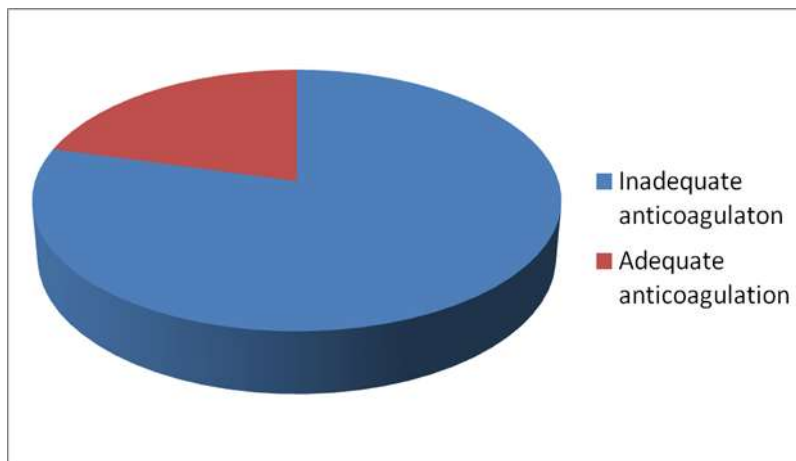


Figure:4 shows incidence of thrombosis according to the valve location

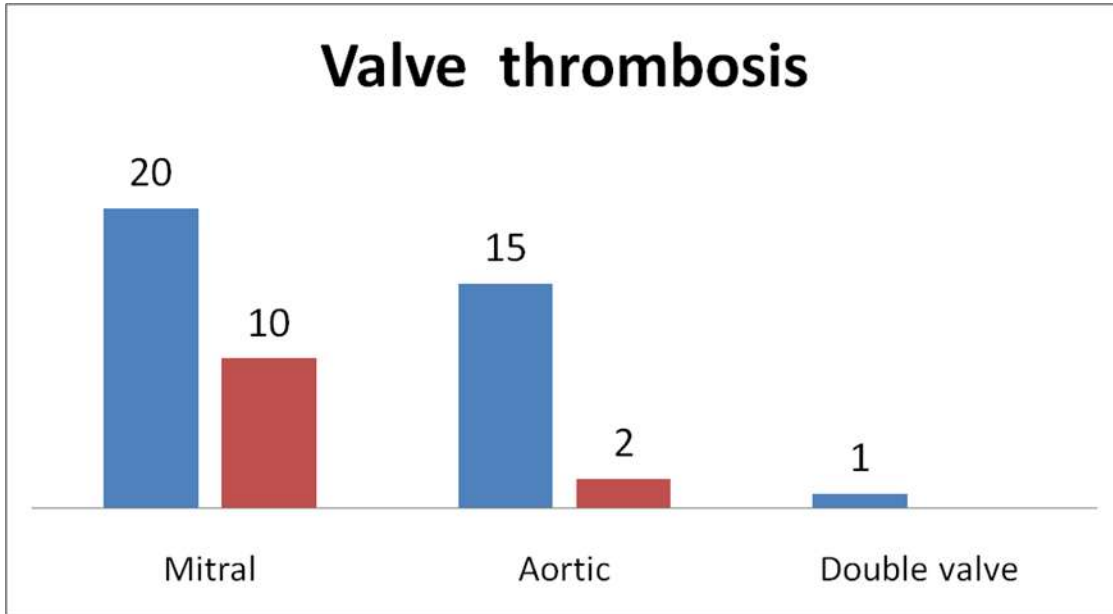


Figure :5shows the various causes of prosthetic valve thrombosis

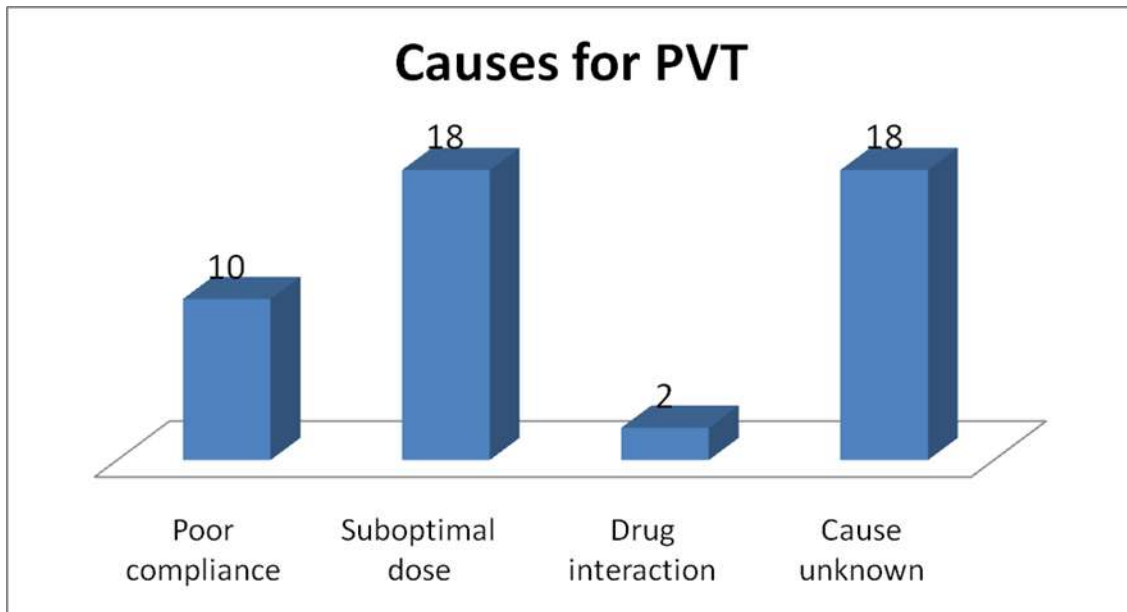


Figure:6 shows clinical profile of the prosthetic valve thrombosis patients

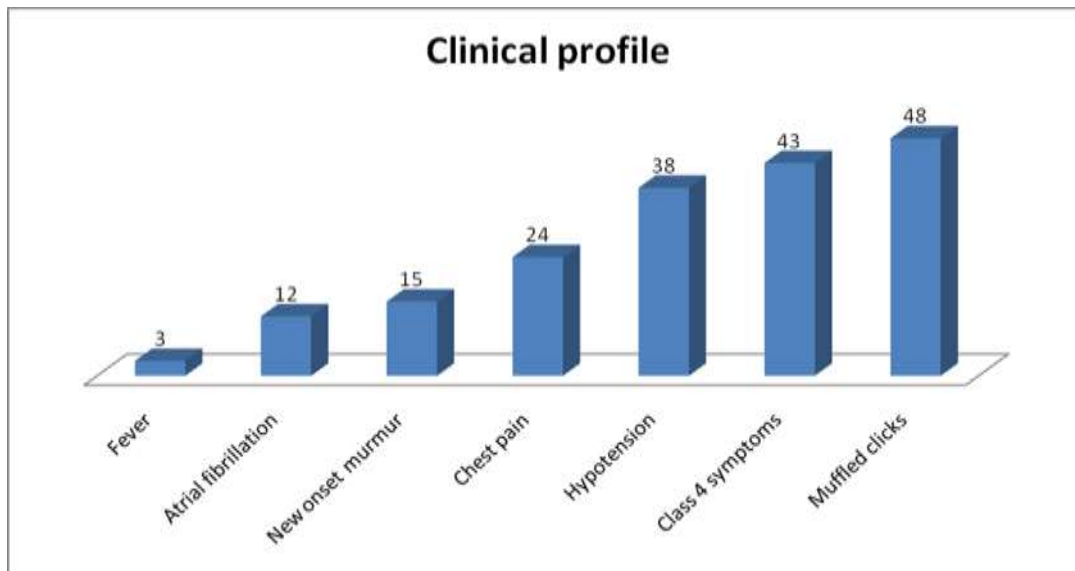
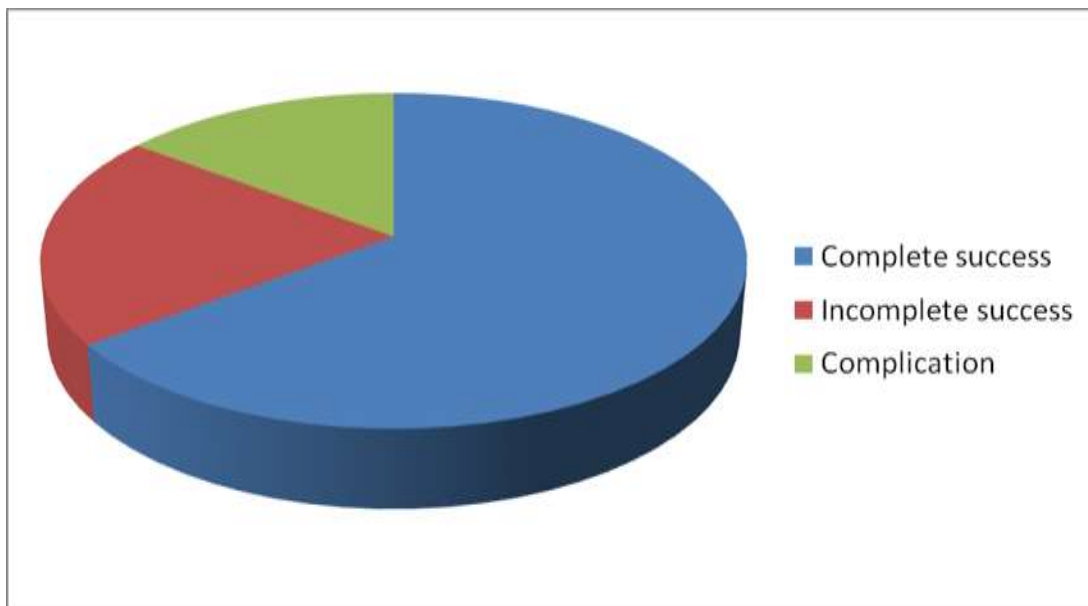
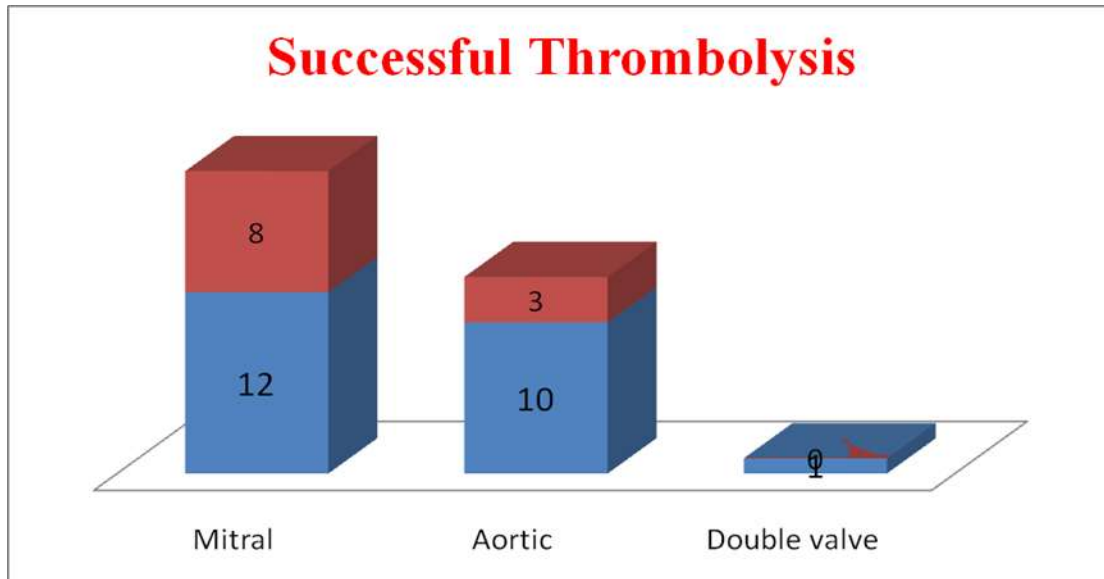


Figure :7shows percentage of patients with various levels of success of thrombolysis



**Figure :8shows successful thrombolysis according to location of thrombus**

## Discussion

PVT is a life threatening situation. Prompt earlier diagnosis followed by rapid treatment will save the life. Management of severe rheumatic heart disease by prosthetic valve implantation does not mean the patient is cured. With the implantation of artificial valves, a disciplined protocol for follow up and maintenance of anticoagulation levels are the important task. [11] With more than 3, 00,000 valve replacements done worldwide there arise a new group of patients called prosthetic valvular heart disease patients. These patients has to be managed with high levels of health education about the valves, about the anticoagulants, about the necessity of maintaining adequate INR levels and need for regular follow up, food habits etc.[12] In our study, all the 48 patients had bileaflet mechanical valve in various locations such as mitral, aortic. Majority of our patients were males and belong to rural areas in our study. Except for co morbid conditions such as diabetes, dyslipidemia and tuberculosis in a few patients, majority of our patients were free of associated diseases. About 73% of our patients presented with PVT within one year of valve replacement. Thus surgery related issues and post operative care, post operative monitoring of anticoagulation, follow up and importance of maintaining INR levels are areas

to be intervened. 2 patients had pulmonary tuberculosis and were taking anti tuberculosis drugs. Drug interaction of acenocoumarol with rifampicin could be a cause for low PT/INR in these patients.[13] Clinically all our patients had muffling or absence of prosthetic valve sounds. Most of the patients presented with pulmonary edema, class IV symptoms and hypotension. About 25% of patients had atrial fibrillation at presentation, which were new onset. Thus atrial fibrillation could be a predisposing factor. 3 of our patients had fever of high degree during presentation. Fever leading to dehydration could also be a contributor for PVT.[14] In our study, about 63% of patients with PVT had prosthetic valve at mitral location and 35% had aortic prosthetic valve. Since prosthetic valve at mitral position is prone to thrombosis, our study also confirmed it On analysing the records available with the patients we found that about 42% had infrequent follow up. Thus a greater emphasis should be placed on educating the patient for the need of follow up. 79% of our patients during presentation had INR of <2.5. Thus a major reason for PVT in our study is inadequate anticoagulation. In our study 34 (70.8%) patients underwent thrombolysis with Streptokinase. Treatment options were decided according to the guidelines. And the thrombolytic therapy was given



according to the protocols followed by heparin and warfarin.[15] The recent review of Lengyel et al. of 200 published reports of left- sided prosthetic heart valve thrombolysis showed an 82% initial success rate, an overall thromboembolism rate of 12%, and a mortality rate of 10%. This consensus conference indicates that FT of left-sided PVT is acceptable for critically ill patients in whom surgical intervention carries high risk or in patients with contraindications to operation. Several studies have examined the role of thrombolysis in the management of PVT. [16]Recently, Roudaut and coworkers conducted a retrospective study of 110 patients treated with fibrinolytic therapy and concluded that the treatment should be reserved for selected patients (those with tricuspid thrombosis, critically ill patients, and patients with contraindications to surgical intervention).Thrombolysis was successful with return of full leaflet mobility in 22 patients (64.7%). Partial return of leaflet mobility in 7 patients (20.6%). 5 patients died of complications (14.7%) in our study.[17] When analyzed the success of thrombolytic therapy according to valve location it has been found that 60% (12/20) had complete success following thrombolysis of mitral valve prosthesis and 77% (10/13) complete success following thrombolysis in aortic valve prosthesis. One patient with double valve replacement had thrombosis of mitral valve- underwent successful thrombolysis. So, overall thrombolysis is better treatment alternative to surgery in many patients for whom surgery could not be performed. 5 (about 15%) patients who were in the thrombolysis arm died due to bleeding complication (3 patients) and cerebral embolism (2 patients).14 (10 mitral and 4 aortic) patients underwent surgery (29.2%). Surgery was done in the form of simple thrombectomy in 8 patients (57%) and valve replacement in remaining 6 patients (43%). 2(14%) patients who underwent valve replacement died.[18] Patients with PVT have high mortality. The commonest predisposing factors for PVTs are inadequate anticoagulation and poor patient compliance. Thus underscoring the need for both patient- and physician- oriented education. Thrombolysis is a reasonable and valid alternative therapy. Surgical intervention may be needed in many patients with PVT. In short regular follow up, periodic monitoring of INR and adjusting it to the ideal level and stable diet pattern play important role

in preventing complications of prosthetic valves. [19,20]

### Conclusion

The incidence of PVT is higher and is about 1.2 per 1000 patient years. The major risk factors for PVT observed in our study are inadequate anticoagulation, lack of follow up and patient prosthesis mismatch. Regarding treatment thrombolysis is a reasonable alternative for surgery with nearly 80% success rate. As the rheumatic heart disease is very much prevalent in India, prosthetic heart valves implantation rate is increasing every year due to high incidence of RHD in India. Inadequate anticoagulation, lack of follow up, non compliance, lack of health education continues to be the major factors for PVT. Technical and lesion related factors are also important as many cases present early after surgery. So, special care should be taken to avoid patient prosthetic mismatch. Clinical recognition of PVT still plays a vital role, as subtle signs like increase in dyspnea and muffling of clicks may be picked up at bedside and leads to suspicion of PVT. Diagnostic tools such as echocardiography (TTE, TEE) play a vital role in diagnosis of PVT through detection of increased gradients and appearance of new regurgitation and visualization of mobility of leaflets. Thrombolytic therapy can be considered as an effective initial intervention (In spite of being class IIb indication as per AHA). Surgery should be recommended for valve dehiscence, large thrombus and for those patients having contraindications to thrombolysis. Emergency cardiac surgery cannot be advocated in most due to logistic reasons. Patient education & better communication are the best tools for prevention of PVT. Physicians need to be aware of various drug interactions with anticoagulants such as warfarin and acenocoumarol.

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