



Review Article

## STUDY OF CLINICAL PROFILE AND OUTCOMES OF FIBRINOLYSIS IN PROSTHETIC VALVE THROMBOSIS

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### ABSTRACT

**Background:** There is a high prevalence of rheumatic heart disease in young in India and the majorities undergo valve replacement surgery at a young age compared to developed countries. Prosthetic Valve thrombosis (PVT) is a pathological entity characterized by thrombus formation on the prosthetic structures, with subsequent PV dysfunction with or without thromboembolism (TE). Obstruction to prosthetic heart valve could be due to thrombus, pannus formation, vegetation, or patient prosthesis mismatch. The treatment options for PVT include fibrinolysis, anticoagulation and surgery. Due to the lack of larger prospective studies and randomized trials, the choice of treatment for PVT remains controversial. This study aims to evaluate the clinical presentation, diagnostic features, treatment strategies, complications of prosthetic heart valve thrombosis (PHVT) and to determine efficacy, outcomes and complications of thrombolytic therapy during hospital stay. **Methodology:** This study is an observational and prospective study conducted between January 2021 to June 2022 for period of 18 months at king George Hospital, which included 115 in patients with prosthetic valve thrombosis. The statistical analysis was done in MS Excel and SPSS and the descriptive analysis was carried out by standard deviation in quantitative variable, proportion and categorical variable. **Results:** The mean age of patients was 40+/-1.927(+/-4.82) with an age range of 20-80 years. Out of 115 patients 39.2% of patients were females and 60.8% were males. 48.7% of the patient's developed thrombosis after more than one year of valve surgery and 51.3% of patients developed thrombosis before 1 year of surgery. Mitral valve thrombosis was seen in 95 patients (82.6%), aortic valve thrombosis in 11 patients (9.6%) 9 patients ( 7.8%) had double valve replacement. Thrombolysis with Streptokinase in Mitral PVT, 35 patients had complete response, 16 patients had partial response and 10 patients were dead/failed response. Thrombolysis with Tenecteplase in Mitral PVT, 18 patients had complete response, 6 patients had partial response and 3 patients were dead/failed response. **Conclusion:** Early clinical recognition of PVT plays an important role in the management of Prosthetic valve thrombosis, as subtle signs like increase in dyspnoea and muffling of clicks may be picked up at bedside and leads to suspicion of PVT. Thrombolytic therapy can be considered as an effective initial intervention and surgery should be recommended for valve dehiscence, large thrombus and for those patients having contraindications to thrombolysis. Regular follow-ups with anticoagulation maintenance are of prime importance in prevention of Prosthetic valve thrombosis.

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### INTRODUCTION

Thrombosis of prosthetic heart valves is a serious complication with high morbidity and mortality. Valve thrombosis is any thrombus in absence of infection attached to or near an operated valve that occlude part of the blood flow path or that interfere with function of the valve<sup>1</sup>. Mechanical valve thrombosis generally occurs in the setting of sub therapeutic anticoagulation or with chronic pannus in growth.<sup>1</sup>The annual incidence valve thrombosis in mechanical valves is 0.5% to 1%. Mortality in patients presenting with acute mechanical valve thrombosis is over 30%.<sup>2</sup> Patients may be asymptomatic or may present with worsening dyspnea, cardiogenic shock ,or

thromboembolic events, some patients may notice diminished intensity of earlier clearly audible click. Echocardiography is required to check transvalvular gradient and grade of valvular insufficiency<sup>2-4</sup>

Treatment options for PVT include fibrinolysis, anticoagulation and surgery. Due to the lack of larger prospective studies, choice of treatment for PVT remains controversial. In many other developing countries, thrombolysis is still the treatment of choice because of its ease of availability and the limitations with surgery (long-waiting period and higher cost). For right sided PVT, fibrinolytics are first choice of the therapy because they are successful in 80%-100% of treated patients<sup>2-5</sup>. For left sided PVT include surgery

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(thrombectomy or valve replacement), fibrinolytic therapy or heparin.

There are no randomized trials comparing these modalities as all modalities are associated with high risk.

**Aims and Objectives**

1. To evaluate the clinical presentation, diagnostic features, treatment strategies and complications of prosthetic heart valve thrombosis
2. To determine efficacy, outcomes and complications of thrombolytic therapy during hospital stay.

**METHODOLOGY**

**Study Design:** Observational and prospective study

**Study Period:** This study was conducted from January 2021 to June 2022 for a period of 18 months.

**Sample Size:** In-patients presenting with prosthetic valve thrombosis to the department of Cardiology in King George Hospital, between January 2021 to January 2022 fulfilling inclusion and exclusion criteria were included after taking informed consent. A total of 115 patients were taken.

**Inclusion criteria**

- Age >18 years with Prosthetic heart valve thrombosis
- Informed consent
- No participation in another study

**Exclusion criteria**

- Any previous intracranial hemorrhage
- Known structural cerebral vascular lesion (e.g., arteriovenous malformation)
- Known malignant intracranial neoplasm (primary or metastatic)
- Ischemic stroke within 3 months except acute ischemic stroke within 4.5hours
- Suspected aortic dissection
- Active bleeding or bleeding diathesis (excluding menstruation)
- Significant closed-head or facial trauma within 3 months
- Intracranial or intraspinal surgery within 2 months
- Severe uncontrolled hypertension (unresponsive to emergency therapy)
- Use of streptokinase within last 6 months

**Data Collection**

This study will be conducted at King George Hospital, Visakhapatnam after taking written informed consent from the patients and approval from Institutional ethics committee. Data will be collected as per pre-set proforma containing epidemiological information (age, sex, occupation, and place),detailed medical history, risk factors, clinical examination and relevant investigations like complete blood picture LFT,RFT,PT/INR,CHEST X RAY,2D ECHO,TEE and CINE FLUROSCOPY.

**Statistical Methods:** Data was entered in Microsoft MS Excel and analysed with SPSS software. Categorical data was expressed in proportions. Descriptive analysis was carried out by standard deviation in quantitative variable, proportion and

categorical variable. Data was also represented using appropriate bar diagrams and pie diagrams.

**OBSERVATIONS AND RESULTS**

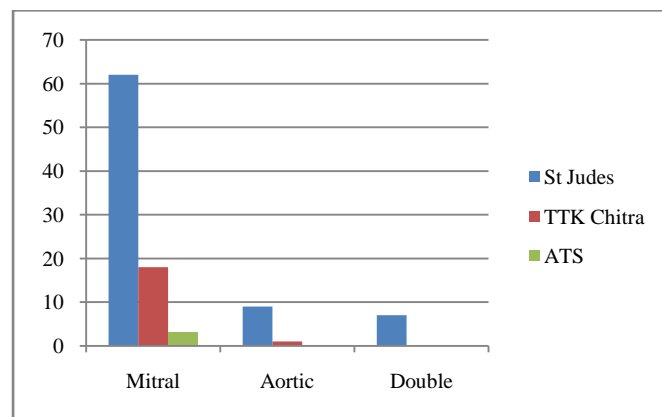
The mean age of patients was 40+/-1.927(+/-4.82) with an age range of 20-80 years. Out of 115 patients 39.2% of patients were females and 60.8% were males 48.7% of the patients developed thrombosis after more than one year of valve surgery and 51.3% of patients developed thrombosis before 1 year of surgery. The majority of patients 73.9% belonged to rural areas in our study. Among 115 patients, 85 patients (65.2%) were drug compliant and 30 patients (34.8%) were drug non-compliant 6 out of 30 non-compliant patients (20%) had completely stopped taking medications.

Mitral valve thrombosis was seen in 95 patients (82.6%), aortic valve thrombosis in 11 patients (9.6%) 9 patients (7.8%) haddouble valve replacement out of which 3 patients had thrombosis of both the valves,4 patients had Mitral valve thrombosis and 2 patients had Aortic valve thrombosis, as shown in Table 1.

**Table 1** Prosthetic valve thrombosis in accordance with valve location

	Patients with PVT	Percentage
Mitral	95	82.6%
Aortic	11	9.6%
Double	9	7.8%
	115	100%

Among all prosthetic Mitral Valves, 61.7% had St Jude'sleaflet valve, 17.4% were TTK Chitra tilting disc type and 3.5% were ATS. Amongaortic prosthetic valves 8.8% had St Judes bileaflet, 0.8% had TTK Chitra tilting disc type. Among dual valve replacements 7.8%were St Judes, as shown in Figure 1.



**Figure 1** Shows the type of prosthetic valve

Atrial fibrillation was found in 28% patients, hypotension in 20% patients, chest pain in 19%patients, fever in 4% patients, 100% patients presented with diminished click. Dyspnoea was the presenting complaint in all the patients. 46(40%) patients presented with NYHA class III symptoms, 59(51.3%) presented with NYHA class IV, and 10(8.7%) presented with class II symptoms.

A suboptimal therapeutic international normalized ratio was found in 87 % of valve thrombosis. Most of the patients had defaulted on their consumption of oral anticoagulant drugs.115 (100%) patients were treated with thrombolytic therapy and

anticoagulants. Streptokinase was used as a thrombolytic agent in 77 (66.9%), Tenecteplase 31(26.9%) and heparin alone in 7(6.2%) as shown in Figure 2.

In our study,49(63.6%) patients who received thrombolysis with streptokinase had a complete response, 18(23.4%) had a partial response and 10(13%) patients had no response to treatment.20 patients(64.5%) who received thrombolysis with Tenecteplase had a complete response, 7(22.5%) had a partial response and 4 patients(13%) had no response to treatment.

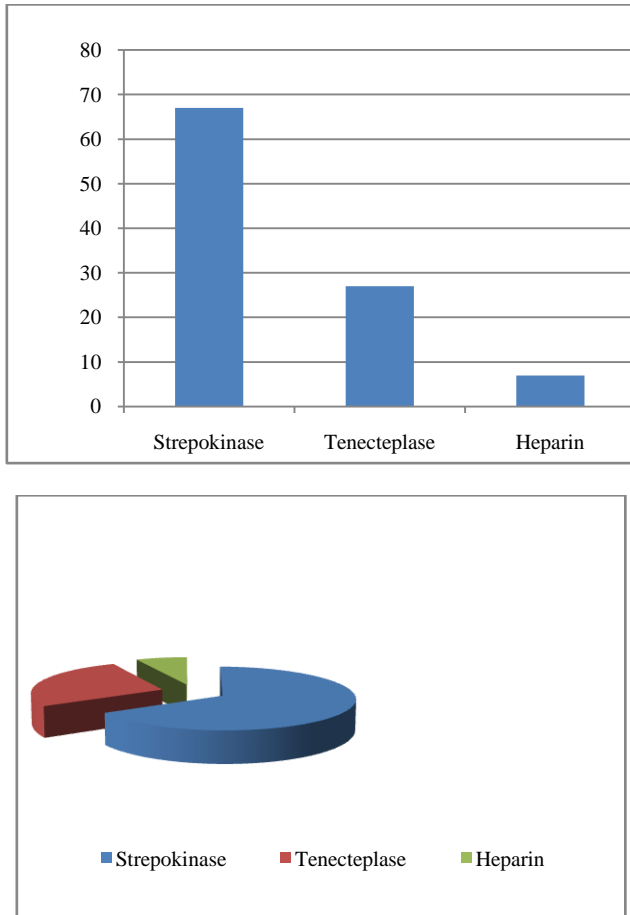


Figure 2 Thrombolytic agents and anticoagulants

4 patients(57.2%) who received heparin had a complete response, 1(14.2%) had a partial response and 2(28.6%) patients had no response to treatment.73 patients(63.4%) had complete clinical success,26(22.6%) had a partial response to treatment and 16(14%) had no response to thrombolytic therapy, as shown in figure 3.

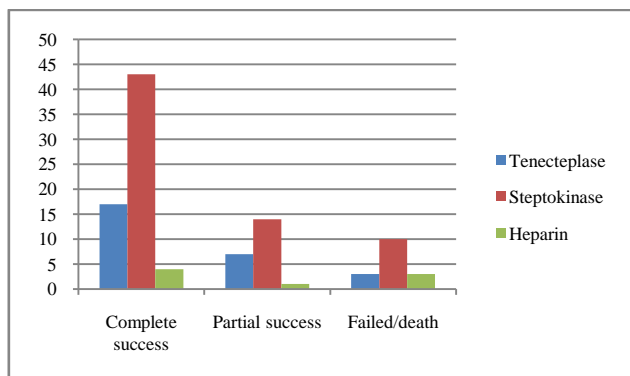


Figure 3 Outcome

Thrombolysis with Streptokinase in Mitral PVT, 35 patients had complete response, 16 patients had partial response and 10 patients were dead/failed response. Thrombolysis with Tenecteplase in Mitral PVT, 18 patients had complete response,6 patients had partial response and 3 patients were dead/failed response.

Thrombolysis with Streptokinase in Aortic PVT,8 patients had complete response,1 patient had partial response. Thrombolysis with Tenecteplase in Aortic PVT,1 patient had partial response and 1 patient had failed response. Thrombolysis with Streptokinase in DVR PVT,6 patients had complete response,1 patient had partial response. Thrombolysis with Tenecteplase in DVR PVT,2 patients had Complete response. The average mean gradient across stuck aortic valve before thrombolysis was 48+/-10.123(+/-20.69%) and stuck mitral valve was 17.07+/-0.952(+/-5.57%). Post successful fibrinolysis, the mean gradient across the aortic valve was 18.63+8.963(+/-48.10%) and mitral valve 3.77+/-0.848(+/-12.34%) at 95% confidence interval.

In our study 21 had stroke, 8 had major bleeding, 5 had minor bleeding and 2 had peripheral embolism, as shown in figure 4. Major fatal complication was defined as all cause in-hospital mortality. Fatal major complications included intracranial haemorrhage (ICH), systemic thromboembolism, ischaemic stroke and other major bleeding as per the International Society on Thrombosis and Haemostasis criteria.<sup>6</sup> non-fatal minor complications were defined as minor bleeding and transient ischaemic attack. All patients with a suspected ischaemic stroke or ICH underwent brain imaging.

- Duration of therapy was 24hours in 63 patients, 18hours in 27 patients and 72hours in 25 patients.
- Majority of patients (70%) had dilated left atrium on admission.
- Nearly 70% of patients had good left ventricular (LV) function, only 10% patients had moderate-to-severe LV dysfunction.
- Around 40% patients had moderate-to-severe pulmonary arterial hypertension (PAH) on admission.
- After treatment, only 8% patients had residual moderate PAH.

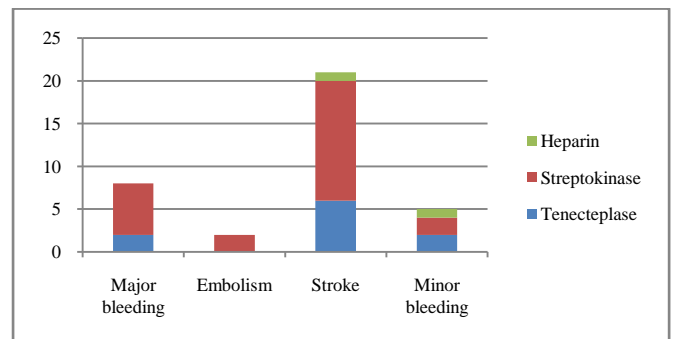


Figure 4 Complications

## DISCUSSION

Majority of the patients in our study were relatively young. 60% patients were below 40 years of age due to high

prevalence of rheumatic heart disease in young patients in our country and majority of patients undergo valve replacement at young age compared to developed countries. Valvular heart diseases affect more than 100 million people around the globe and are associated with significant mortality and morbidity.<sup>7</sup> Obstruction to prosthetic heart valve could be due to thrombus, pannus formation, vegetation or patient prosthesis mismatch. Prosthetic Valve thrombosis (PVT) is a pathological entity characterized by thrombus formation on the prosthetic structures, with subsequent PV dysfunction with or without thromboembolism (TE).<sup>8-10</sup> There is a high prevalence of rheumatic heart disease in young in India and the majority undergo valve replacement surgery at a young age compared to developed countries.<sup>11-12</sup>

The mean age of our patients was 40+/-1.927(+/-4.82) and male predominance. Most of the studies of PVT from the Indian sub-continent belonging to younger age group in 3rd and 4th decade and female dominance, as shown in table 2.<sup>13-16</sup> Mean age was 58±12 in a study from Montreal.<sup>17</sup> The mean age of patients was 46.62±13.6 from Vaishali Verma *et al* study.<sup>18</sup>

**Table 2** Comparison of Mean age in different studies

	Present study	Montreal	Vaishali Verma
Mean age +/- 2SD	40+/-1.927	58+/-12	46.62+/-13.6

The majorities of patients belonged to rural backgrounds and have poor availability of health resources and medical care. This might contribute to drug default by the patient. In our study Out of 115 patients, majority of patients 73.9% belonged to rural area. 85 patients (62.5%) were regular and 30 patients (34.8%) were irregular in drug intake and out of which 6(20%) had completely stopped taking medications. Poor drug compliance also emerged as a significant risk factor in studies done by Durrleman *et al* reported 10 out of 39 were defaulters and Manjula *et al* reported 23 out of 26 patients were non-compliant.<sup>17-18</sup>

Majority of studies have cited sub-therapeutic INR as a major risk factor for the development of PVT which was mainly due to irregular follow-up and poor treatment compliance. In our study a suboptimal therapeutic international normalized ratio was found in 87 % of valve thrombosis. Most of the patients had defaulted on their consumption of oral anticoagulant drugs. Studies from India show variable rates of inadequate anticoagulation ranging from 41.5 to 90.3% [18-20]. Egbe *et al* found inadequate anticoagulation in 48% of patients with PVT.<sup>19</sup>

In our study Atrial fibrillation was found in 28% patients, Hypotension in 20% patients, chest pain in 19% patients, fever in 4% patients, all patients of PVT presented with dyspnoea and a muffled click on examination. Most common presentation is dyspnoea in majority of studies. Most of the patients presented with NYHA class III and Class IV symptoms. In our series, most patients were in NYHA class IV at presentation 59(51.3%) whereas in series by Nawale *et al*. maximum patients fell under NYHA class IV (52.4%).<sup>16</sup> In the series by Durrleman *et al*, they reported maximum number of patients were in class III or IV at presentation (87%)<sup>20</sup>. Similarly in the study published by Gupta *et al*, reported that 46.4% of patients were in NYHA class III and 24.5 % of patients were in NYHA class IV at the time of presentation.<sup>21</sup>

In our study, thrombosis of the mitral valve was seen in 95 patients (82.6%), 11(9.6%) developed thrombosis of the aortic valve and 9 patients (7.8%) had thrombosis of the double valve, as shown in table 3. In Mansuri, *et al.*: PHVT, fibrinolysis, or surgery study, most cases had mitral valve thrombosis (91.5%), whereas 8.5% patients had aortic prosthesis thrombosis.<sup>17</sup> In a study by Gupta *et al.*, 87.3% of the PVT episodes occurred in the mitral position. Several studies have confirmed that mitral PVT is 2–3 times more frequent than thrombosis of an aortic prosthesis.<sup>22</sup> A search of at least 200 published reports of left-sided prosthetic valve fibrinolytic therapy showed an 82% initial success rate, an overall thromboembolism rate of 12%, and a stroke rate of 5%–10%, with 6% death, 5% major bleeding episodes, and 11% recurrent thrombosis.<sup>23</sup> In Mansuri, *et al* study, most cases had mitral valve thrombosis (91.5%), whereas 8.5% patients had aortic prosthesis thrombosis.<sup>17</sup>

**Table 3** Thrombosis in accordance with valve location in different studies

	Mitral PVT	Aortic PVT
Present study	82.6%	9.6%
Mansuri	91.5%	8.5%
Gupta <i>et al</i>	87.3%	

In our study, 115 patients (100%) were treated with thrombolytic therapy. Streptokinase was used as a thrombolytic agent in 77 (66.9%), tenecteplase 31(26.9%) and anti-coagulant heparin in 7(6.2%), as shown in table 4. In our study, 49 patients (63.6%) who received thrombolysis with streptokinase had a complete response, 18(23.4%) had a partial response and 10 patients (13%) had no response to treatment. In our study 20 patients (64.5%) who received thrombolysis with Tenecteplase had a complete response, 7(22.5%) had a partial response and 4 patients (13%) had no response to treatment. In our study 4 patients (57.2%) who received Heparin had a complete response, 1(14.2%) had a partial response and 2 patients(28.6%) had no response to treatment. In Vaishali Verma *et al* study Streptokinase was used in the majority of patients 66.7% and Tenecteplase and reteplase was used in 2 patients each.<sup>20</sup> In a study conducted by Kathirvel *et al*. 76.9 % of patients were thrombolysed with STK and 23.1 percent were thrombolysed with TNK.<sup>24</sup> In the study conducted by Hiracharan *et al*. 86.9 % of patients were thrombolysed with STK and 13.1% were thrombolysed with TNK.<sup>16</sup>

**Table 4** Thrombolytic agents used in different studies

	Present study	Vaishali verma <i>et al</i>	Kathirvel <i>et al</i>	Hiracharan <i>et al</i>
Streptokinase	66.9%	66.7%	76.9%	86.9%
Tenecteplase	26.9%	16.6%	23.1%	13.1%

In the current series whenever STK was given, 2.5 lakh IU intravenous bolus for 30 minutes followed by slow intravenous infusion at the rate of 1 lakh IU/hr was administered. Extended thrombolysis up to 72 hours was instilled in case of failed response. Out of 115 patients, 73 patients(63.4%) had complete clinical success, 26(22.6%) had a partial response to treatment and 16(14%) had no response to thrombolytic therapy.

Thrombolysis with Streptokinase in Mitral PVT, 35 patients had complete response, 16 patients had partial response and 10 patients were dead/failed response. Thrombolysis with

Tenecteplase in Mitral PVT, 18 patients had complete response, 6 patients had partial response and 3 patients were dead/failed response.

Thrombolysis with Streptokinase in Aortic PVT, 8 patients had complete response, 1 patient had partial response. Thrombolysis with Tenecteplase in Aortic PVT, 1 patient had partial response and 1 patient had failed response. Thrombolysis with Streptokinase in dual valve replacement (DVR) PVT, 6 patients had complete response, 1 patient had partial response.

Thrombolysis with Tenecteplase in DVR PVT, 2 patients had complete response. Roudaut *et al.* reported in their study that full success with one or more consecutive thrombolytic regimens was obtained in 90 out of 127 cases (70.9%): 37/46 (80%) aortic valve and 52/80 (65%) mitral valve.<sup>23</sup> Hering *et al.* reported in their study that fibrinolytic therapy resulted in complete clinical and hemodynamic recovery in approximately 76% of patients with left-sided and 71% of those with tricuspid PVT.<sup>18</sup>

Success rates were slightly higher in aortic than in mitral valve prostheses, probably because of the greater degree of thrombotic burden necessary to cause significant obstruction in mitral valve prostheses, as shown in table 5. Overall success rate of fibrinolytic therapy was 65.5% and mortality was 14.8% in Mansuri, *et al.* study.<sup>17</sup>

**Table 5** Comparison of complete success following thrombolysis in different studies

	Present study	Roudaut <i>et al.</i>	Hering <i>et al.</i>	Mansuri <i>et al.</i>
Complete success%	63.4%	70.9%	76%	65.5%

The average mean gradient across stuck aortic valve before thrombolysis was 48+/-10.123(+/-20.69%) and stuck mitral valve was 17.07+/-0.952(+/-5.57%). Post successful fibrinolysis, the mean gradient across the aortic valve was 18.63+8.963(+/-48.10%) and mitral valve 3.77+/-0.848(+/-12.34%) at 95% confidence interval. Fibrinolysis was delayed by 24–48 hours in a subset of haemodynamically stable patients with a high INR >2.5 and initiated at a lower INR (mean 2.42 ± 0.89) with patients receiving unfractionated heparin in the interim period. For 3 patients with high INR Vitamin K was given and thrombolysed with Tenecteplase in 2 patients and streptokinase in one patient.

Atrial fibrillation is one of the major causes for thromboembolism, and it is also risk factor for PVT. In our study, around 28% patients had atrial fibrillation or flutter, and remaining 72% had sinus rhythm. Here, we have relatively higher prevalence of atrial fibrillation and flutter in PHVT patients. In Mansuri *et al.* study, around 36.9% patients had atrial fibrillation or flutter, and remaining 63.1% had sinus rhythm.<sup>19</sup> In our study 21 patients had stroke, 8 patients had major bleeding, 5 patients had minor bleeding and 2 patients had peripheral embolism was seen.

## CONCLUSION & SUMMARY

- Major risk factors for PVT are inadequate anticoagulation, lack of follow up and patient prosthesis mismatch.
- Thrombolysis is a reasonable alternative for surgery with nearly 63.4% success rate.

- Clinical recognition of PVT still plays a vital role, as subtle signs like increase in dyspnoea 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.
- In patients with left-sided PVT, fibrinolysis unless contraindicated can be considered as an effective and acceptable alternative to surgery even in patients with NYHA Class III/IV, especially in developing countries or in centres with limited resources, where multiple factors such as surgical availability, financial cost, and operative mortality are to be weighed while deciding the treatment
- 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.
- Complete and partial success rates of TT with TNK in mitral PVT were equal to SK.
- Finally, in the era of advancement in communication systems patient doctor relation can be improved and will play a crucial role in anticoagulation maintenance and thus preventing prosthetic valve thrombosis.

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