



**ORIGINAL RESEARCH PAPER**

**Cardiology**

**TO STUDY THE CLINICAL AND ETIOPATHOLOGICAL PROFILE IN PROSTHETIC VALVE DYSFUNCTION-A SINGLE CENTRE EXPERIENCE.**

**KEY WORDS:** Prosthetic valve, Thrombosis , Anticoagulation, International Normalized Ratio, PVD- Prosthetic valve dysfunction PVT- Prosthetic valve thrombosis PV- Prosthetic valve

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**ABSTRACT**

Valvular heart disease affects millions has significant morbidity and mortality, further increased even after valve replacement when associated with Prosthetic valve dysfunction(PVD). The risk of Prosthetic valve thrombosis(PVT) and thromboembolic events is higher for prosthetic valve(PV) in mitral position. The annual incidence rate of PVT ranges from 0.1% to5.7%. Determining the main etiology of PVD is crucial as the treatment differs for each also its important to identify the optimal antithrombotic therapies to prevent PVD/PVT. In our observational study, 32 patients enrolled. (21)65.6% are female and (11)34.4% males with age from 20 to 66 yrs. Most PVD noted in Mitral Valve(93.8%). Non obstructive Prosthetic Valve Thrombosis is most common PVD seen in 16(50%)patients, 8(25%) had obstructive Prosthetic Valve Thrombosis, 6(18.75%) had Prosthetic Valve Endocarditis/vegetations, 2(6.25%) had pannus formation.Thromboembolic features seen in 3 patients. 12(37.5%) patients are asymptomatic, 6(18.75%) with mild dyspnea and 6(18.75%) with heart failure and shock. Mean INR is 1.58±0.6 with only 5(15.62%) on therapeutic range. The mean INR with Non obstructive PVT is 1.91±0.4 and with obstructive PVT is 1.0±0.2. 27(84.36%) on lower side of therapeutic INR and the frequency of monitoring is less. 18(56.25%) had normal PV gradient and the gradient increased in 14(43.75%) patients. The mean mitral valve (MV) gradient is 9.5±6.9, MV Vmax 2.2±0.6, MV VTI 2.5±0.6, MV PHT 158±91.9, MV EOA 1.65±0.8. Thrombus size varies from 2 to 8.1mm in diameter. 26 patients had TTK chitra valve and 6 patients with St Jude- bileaflet, and data is limited to compare both. On treatment 6 patients underwent thrombolysis, 2 reoperated, 24 heparinized and acitrom dose titred , one patient expired, 6 patients with PV endocarditis/vegetation managed with higher antibiotics and anticoagulation. Prosthetic valve dysfunction is not uncommon. Non obstructive PVT is the commonest PVD noted missed PVT results in increased mortality

**INTRODUCTION**

Valvular heart disease affects more than 100 million persons worldwide, and is associated with significant morbidity and mortality'. The overall age-adjusted prevalence of mitral or aortic valvular heart disease is estimated to be 2.5% in the general population of the United States<sup>2</sup>, with a prevalence exceeding 10% in subjects over 75 years of age Surgical valve replacement.

PV dysfunction is a complication of mechanical or biological prostheses<sup>3</sup>, which leads to reduced leaflet motion or impaired leaflet coaptation, leaflet thickening, reduced or increased effective prosthesis orifice area leading stenosis or insufficiency, increased transvalvular gradient or regurgitation, with or without development of valve-related symptoms.

The four 4 main etiologies<sup>4,5</sup> are PV thrombosis , fibrotic pannus ingrowth, PV degeneration, PV endocarditis with vegetation formation. These occurs simultaneously and associated with thrombus formation. The determination of the main etiology of PV dysfunction is crucial because the treatment differs for each conditions<sup>6,7</sup>. In a retrospective study <sup>8,9</sup>from India, left-sided prosthetic valve thrombosis (PVT) occurred in 6.1% of patients within 6 months of valve replacement.

The type of PV its anatomical location and patient-specific risks of TE<sup>10,11</sup> and bleeding risks influence the intensity and duration of antithrombotic treatment to prevent PV thrombosis with subsequent PV dysfunction and/or TE. It is important to identify the optimal antithrombotic therapies/strategies to prevent PV dysfunction/thrombosis

<sup>12,13</sup>. To translate this information to provide a perspective on optimal long-term antithrombotic management and supportive measures in the era of valve therapies

**AIM AND OBJECTIVE:**

To study the clinical and etiopathological profile in Prosthetic valve dysfunction

**METHODS:**

**Study Design:** OBSERVATIONAL STUDY

**Inclusion Criteria:**

All the patients who underwent valve replacement with prosthesis Mechanical or bio prosthesis, Patients with or without antithrombotic medications, any type of valve implants

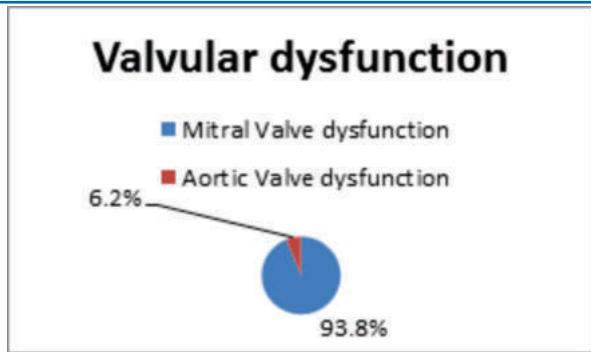
**Exclusion Criteria:**

Patients on Atrial fibrillation, antiarrhythmic medications, Hyper coagulable states, Connective tissue disorder, Pregnant women, Chronic liver or Renal disease

**RESULTS**

The study showed a female predominance (21)65.6 % over males (11)34.4 %. Minimum and maximum age was found to be 20 and 66 years respectively. The mean age was 45.3 ± 12.6 years .Most valve dysfunction noted in Mitral Valve (93.8%).

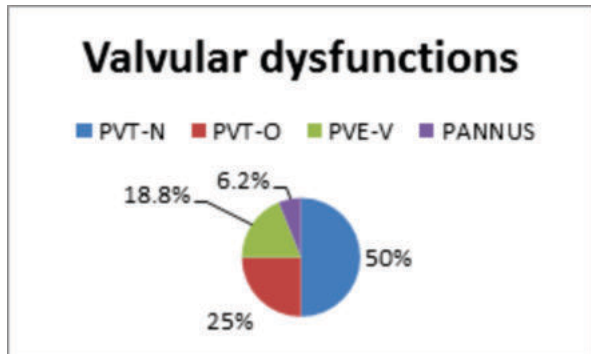
Non obstructive Prosthetic Valve Thrombosis is most common PVD seen in 16(50%) patients.8(25%) patients had obstructive Prosthetic Valve Thrombosis. 6(18.75%) patients had Prosthetic Valve Endocarditis/ vegetations .2 (6.25%) patients had pannus formation .



Thromboembolic manifestations seen in 3 patients, 2 patients with stroke and one patient had peripheral embolization of thrombus and vegetations 12 (37.5%) patients are asymptomatic, 6(18.75%) patients with mild dyspnea and 6(18.75%) patients presented with heart failure and shock.

**Table: Dysfunction types**

	Frequency	Percentage
PVT-N	16	50.0
PVT-O	8	25.0
PVE-V	6	18.8
PANNUS	2	6.2
Total	32	100.0

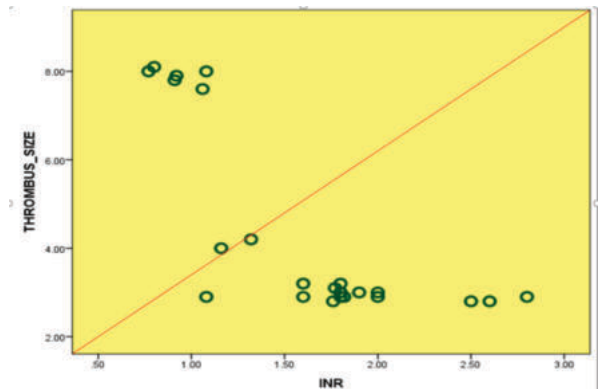


The mean Age(years) at surgery is 40.9 ±11.4. The mean duration of years from valve replacement is 4.4±1.9. The mean INR is 1.58 ± 0.6 with 5(15.62%) patients not taking anticoagulants and 5(15.62%) patients on therapeutic INR range that too on the lower side. The mean INR of patients with Non - obstructive PVT is 1.91±0.4 and for patients with obstructive PVT is 1.0±0.2. Overall of the patients on anticoagulation the INR of 27(84.36%) patients was on the lower side of therapeutic range as per Recommendation and the frequency of monitoring INR very less. Patients with INR of 2.5-3.5 (15.62%) were optimally anticoagulated while the majority nearly 84.36 % had INR<2 (under anticoagulated).

	Minimum	Maximum	Mean	SD	Median	IQ Range
PVT-Na (n=16)	1.08	2.8	1.91	0.4	1.80	1.76, 2.0
PVT-Ob (n=8)	0.77	1.3	1.0	0.2	0.99	0.83, 1.14
PVE-Vc (n=6)	0.77	1.7	1.2	0.3	1.25	0.89, 1.42
PANNUS (n=2)	2.0	2.5	2.25	0.4	2.25	2, -
Total (n=32)	0.77	2.80	1.58	0.6	1.66	1.08, 1.88

Independent t-test used; p-value < 0.001 (a\*b) ; p-value =0.001 (a\*c) ; p-value =0.16 (b\*c) p-value <0.05 is significant

Pearson's Correlation Coefficient	-0.771
p-value	<0.001



The mean acitrome dose (mg) is 1.9±0.9, The mean dose of patients with patients Non - obstructive PVT is 2.5 ± 0.5 and for patients with obstructive PVT is 1.0±1.0. Out of 32 , 18(56.25%) patients had normal PV gradient and the gradient increased in 14(43.75%) patients. The mean MV gradient is 9.5±6.9, MV Vmax 2.2±0.6, MV VTI 2.5±0.6, MV PHT 158±91.9, MV EOA 1.65±0.8 and **Mean AV gradient 2.5 ± 0.5, Vmax 2.5 ± 0.5, DV 2.5 ± 0.5, Acceleration time 2.5 ± 0.5**. The Distribution of size of thrombus in various mitral valve dysfunction range from 2 to 8.1mm in diameter with mean 4.9 ±0.95 with mean size in Non - obstructive PVT is 2.9±0.1 and obstructive PVT is 6.9±1.8. The mean EF is 55.9±7.9 and for patients with Non - obstructive PVT is 60.8± 2.7 and for patients with obstructive PVT is 48±8.7. Out of 32, 26 patients had valve replacement with TTK valve and 6 patients with St Jude- bileaflet, there is limited data to compare both valves. Out of 32, 6 patients underwent thrombolysis, 2 patients underwent redo surgery, remaining 24 patients heparinized and acitrome dose titrated to achieve target INR, one patient with severe valve dysfunction expired, 6 patients with PV endocarditis/vegetation are managed with higher antibiotics and anticoagulation out of which 2 patients had normal valve gradient. Combined PVT and vegetations<sup>14,15</sup> occurred rather than isolated PV Endocarditis/vegetations.

Overall compared to prior Indian studies and registry data – much larger patients were on anticoagulation but only fewer received appropriate anticoagulation<sup>16,17</sup> Lower mortality observed in NOAC group compared to VKA<sup>18,19</sup> and those who didn't receive anticoagulation deserves merit – though given the small patient size, larger studies are needed to confirm this trend<sup>20,21</sup>.

**DISCUSSION**

Prosthetic valve dysfunction is not uncommon - 32 cases could be recorded at a single tertiary care centre in 16 months. Non obstructive Prosthetic Valve Thrombosis with normal valve gradient is the commonest PVD in the study<sup>22,23</sup>. Dyspnea NYHA II is the most common symptom. Only 5(15.62%) patients are in therapeutic INR remaining 27(84.36%) patients are in lower therapeutic levels suggests poor follow up<sup>24,25</sup> and reduced frequency of INR monitoring<sup>26</sup>. Strict compliance to medication and regular monitoring of INR was lacking in large proportion of patients<sup>27,28</sup>

The current study reflects the poor follow up and poor education of patients regarding INR levels and importance of PV Dysfunction<sup>28</sup>. The impact of COVID - 19 pandemic on presentation and outcomes of patients also plays a role in PVD and also significant decline<sup>29</sup> in admissions with PVT in a regional place.

Current survey suggested there was loss of therapeutic INR achievements and discontinuation of medications. The deleterious effect of late presentation and/or missed PVT during COVID-19 pandemic is likely to manifest itself as a

new cases of heart failure and shock<sup>30,31</sup> and may even result in increased mortality among PV patients. Limitation of this study is small sample size and compared to General included patients presented to our institute only. There is also limited data for comparing the types of valves, the number of patients with St.Jude-Bileaflet are very less than TTK valve. Patients Tricuspid and Pulmonary valve replacement were not included in study also cases with AVR are negligible.

**CONCLUSIONS**

Prosthetic valve dysfunction is not uncommon. Non obstructive PVT is the commonest PVD noted. Only 5(15.62%) patients are in therapeutic INR remaining 27(84.36%) had lower levels suggests poor follow up, compliance and reduced monitoring frequency. missed PVT results in increased mortality. Limitation of this study is small sample size, limited data for comparing the types of valves

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