

A Study of Clinical Profile of Patients with Prosthetic Heart Valve Admitted in Medicine Ward & ICU

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ABSTRACT

Background : Rheumatic valve disease is major cause of valvular disease in India, and prosthetic valve implantation is most common procedure done. But valve implantation is free of risk and inherit multiple complication like Primary valve Failure, Prosthetic valve endocarditis (PVE), Prosthetic Valve Thrombosis & Thromboembolism, Anticoagulation Related Haemorrhage, Mechanical Haemolytic Anaemia.

Aims and Objective : To study the Clinical Profile of Patients with Prosthetic Heart Valves admitted in Medicine Wards & ICU and their in-Hospital Outcome.

Methodology : This cross-sectional observational study was performed at a tertiary care hospital from November 2018 to MAY 2020 after taking approval from ethical committee. Total 45 patients were taken during study and history regarding prosthetic valve, anticoagulation therapy, past history of illness, history of presenting illness, course in hospital and status at the time of discharge was taken.

Results : A total 45 pts. were taken in study in which 25 were male and 20 were female. 44 out of 45 had mechanical valve replaced & only one patient had bioprosthetic valve replaced. 38 (86%) out of 44 pts. had mitral valve replaced, 4 (9%) had Aortic valve replaced and 2 (5%) had both aortic and mitral valve replaced, Prosthetic valve thrombosis was present in 10 (22.22%), Warf induced coagulopathy in 13 (28.88%), AF with FVR in 10 (22.22%), cardioembolic stroke was 1 (.2.2%), brain abcess in 1 (2.2%) endocarditis in 1 (2.2%) & others - 9 (20%).

Conclusion : prosthetic valve implanation is not free of complication and post implantation care is an important and unmet need in patient with prosthetic valves. Prosthetic valve thrombosis is most hazardous and anticoagulant induced bleeding was most common complication with atrial fibrillation with fast ventricular rate was most common reason for repeated hospitalisation admission.

Introduction :

Rheumatic valve disease is major cause of heart valve related surgery in India and prosthetic valve implantation is most common procedure done for diseased valve. The pioneering efforts of Dr. Charles Hufnagel, who made the first successful placement of a totally mechanical valvular prosthesis, started the era of artificial heart valves^{1,2} There are two major type of prosthetic valve implantation done, mechanical and bioprosthetic.

Currently, mechanical valves are preferred except in elderly patients or those who cannot be put on anticoagulant therapy, like women who may still wish to bear children, or patients with bleeding disorders. Complication include, Primary valve

Failure, Prosthetic valve endocarditis (PVE), Prosthetic Valve Thrombosis & Thromboembolism, Anticoagulation Related Haemorrhage, Mechanical Hemolytic Anemia. Primary valve failure may occur abruptly from the tearing or breakage of components or from a thrombus impinging on leaflet mobility. More commonly, valve failure presents gradually from calcification or thrombus formation. Primary valve failure occur in 3-4% of the patients with bioprosthesis within 5 years of implantation and in up to 35% of patients, within 15 years. It is anticipated that most mechanical valves remains functional for 20-30 years. Prosthetic valve thrombosis (PVT) is a serious complication of replaced valves with significant mortality and morbidity. Inadequate anti-coagulation is the common cause for episode, but there is limited data on recurrent PVT. Prosthetic valve endocarditis (PVE) occur in 2-4% of patient, the incidence is 3% in first postoperative year, then 0.5% for subsequent years. Incidence is higher for mitral valve; mechanical and biological valve are equally

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Received on 16th June 2020

Accepted on 24th June 2020

susceptible. This study is done to evaluate the clinical outcome of patients admitted in the hospital with prosthetic heart valves for various reasons.

Methodology :

This cross-sectional observational study was performed at a tertiary care hospital from November 2018 to MAY 2020 after taking approval from the institutional ethical committee. Total 45 patients were included in the study. History regarding prosthetic valve, anticoagulation therapy, past history of illness, history of presenting illness, course in hospital and status at the time of discharge was taken.

Inclusion Criteria : Patients having undergone prosthetic valve replacement (biological & mechanical) requiring hospitalization in Medicine Wards or ICU .

Exclusion Criteria : Patients not giving Consent

Result :

A total 45 patients were included in study (25M / 20F). 44 out of 45 had mechanical valve replaced & only one patient had bioprosthetic valve replaced. 38 (86%) out of 44 pts had mitral valve replaced, 4 (9%) had Aortic valve replaced and 2 (5%) had both aortic and mitral valve replaced **Table 1**. The observed complication were (f1), prosthetic valve thrombosis-10 (22.22%), Warf induced

coagulopathy-13 (28.88%), AF with FVR-10 (22.22%), cardio-embolic stroke-1 (.2.2%), brain abcess-1 (2.2%), endocarditis-1 (2.2%) & others-9 (20%)

The complication were more in elderly patients (age > 50) having atrial fibrillation, the most common complication in that group followed by warfarin induced coagulopathy induced coagulopathy (WIC). **Table 2** shows AGE wise distribution of different complication.

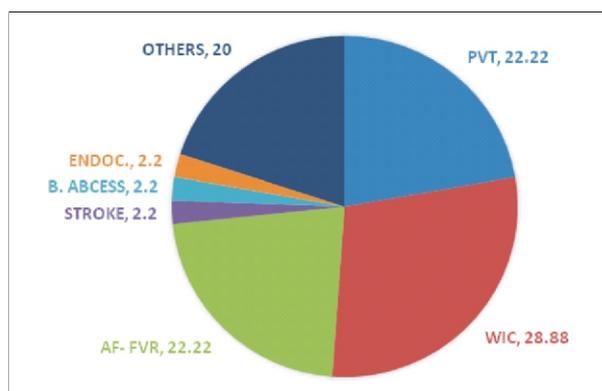


Fig. 1 : Complications Observed during Study (in%)

Prosthetic valve thrombosis was present in 10 (22.22%) patients in which, 6 (60%) were male & 4 (40%) were female. 9 (90%) out of 10 patients had mechanical mitral valve and only 1 (10%) patient had aortic. Among them 4 patients (40%) were between the age of 31-40 years, 2 (20%) patients

Table 1 : Different Type of Valve

MECHANICAL (98%)				BIOPROSTHETIC	
MITRAL (38)				AORTIC	BOTH
CHITRA	ST. JUDES	MEDTRONIC	UNKNOWN		
7	6	2	23	4	2
					1

Table 2 : Age wise distribution of different complication

AGE	PVT	WIC	AF WITH FVR	STROKE/BRAIN ABCESS	ENDOCARDITIS	OTHERS	TOTAL
<20	0	0	0	0	0	0	0
20-30	0	3	0	0	0	0	3
30-40	4	2	1	1	1	2	11
40-50	2	3	2	0	0	2	9
>50	4	5	7	1	0	5	22
TOTAL	10	13	10	2	1	9	45

were between 41 - 50 yrs. and 4 (40%) were above 50 years. 9 (90%) patients are on anticoagulants and 7 (70%) patients had no compliance to anticoagulants. 2 patients had history of comorbidities and 1 had history of old CVE. All patients were admitted to ICU. 6 (60%) pts. presented with NYHA grade 3/4 breathlessness, 3 (30%) pts. presented with grade 2/4 and 1 patient presented with altered mentation. All patient had tachycardia and 7 patients were hypoxemic when admitted, all had raised jugular venous pressure. 6 Patients were in shock (MAP < 65) on admission and 5 (50%) pts. had AF in their ECG on admission. 1 patient had INR > 2 & 7 pts. had INR below 2 and 2 pts. died before any investigation. 3 (30%) pts. had LV dysfunction. Mitral valve gradient was more than > 10 mm Hg in 7 (70%) patients. primary thrombolysis with STK was tried in all pts, 6 (60%) pts. expired on same day of admission and 4 pts. survived and Average duration of stay for survived patients was 6 days. **Warfarin induced coagulopathy was present in 13 patients (6M/7F).** 12 (93 %) out of 13 had mechanical mitral valve replacement and 1 (7%) patient had double valve replaced. All patients had good compliance to anticoagulants. 4 (31%) patients had comorbidities. 11 patients (86%) patients presented with bleeding manifestation, 1 (7%) patient presented with convulsion and 1 (7%) presented with unconsciousness. Ecchymotic patches were present in 10 (77%) patients. 8 (62%) patients had INR in the range of 5-8. 3 patients (23%) had in range in 2-5 & 2 (15%) patients had INR > 8.1 patient (7%) had IC bleed and 1 patient (7%) had Sub-dural hematoma. 1 patient (7%) expired due to IC bleed and rest 12 patients (93%) discharged with the average duration of stay of 7 days. Atrial fibrillation with FVR was present in 10 patients, (5M/5F). 4 of them had comorbidities and 2 had history of old CVE. 7 patients (70%) presented with palpitation while 3 (30%) presented with breathlessness. 9 out of 10 patients had mechanical mitral valve while 1 patient had both mitral and aortic valve replaced. 8 pts. (80%) patients were on anticoagulant with good compliance. None of the patient presented with shock (MAP < 65 mmHg). All 10 patients had INR

between 2-3. 1 patient had H/O old CVE (infarct). 3 patients had LA diameter (in mm) of 31-40, 4 patient had 41-50 & 3 pts. had > 50. All patients were admitted to ICU and then transferred to wards after rate control and then discharged with average duration stay of 4 days. Only 1 patient presented with stroke, who was altered consciousness on admission, and had aortic valve replaced done, patient was on anticoagulants with INR of 2.3 on admission. Patient was in AF with rate controlled, patient was discharged after a stay of 6 days. 1 patient presented with brain abscess, but prosthetic valve endocarditis was not documented and also blood culture shown no growth and patient was transferred to neurosurgery for further management. **Endocarditis** - only 1 patient presented with endocarditis, came with h/o fever and palpitation. Echo showed vegetation on roof of prosthetic mitral valve, but no growth was present on blood culture, and patient was admitted for 21 days. 2 pts. presented with arterial thrombi. Both of them were not on anticoagulation and both of them had INR below 2. 1 patient presented with digoxin toxicity and 1 with diltiazem overdose. 1 patient presented with acute gastroenteritis with shock, and one with acute viral hepatitis. One patient presented with congestive cardiac failure with cardiogenic shock and he expired. 1 patient with bioprosthetic valve presented with urinary tract infection.

Table 3. showing Demographic characteristics of patient taken in study.

Table 4. showing Symptoms with which patients presented in study population

Table 5. showing Hemodynamic parameters observed during study.

Discussion :

Shortly after the heterotopic prosthetic valve implantation by Hufnagel in 1954, on September 21, 1960, Starr performed the first successful orthotopic valve replacement in the mitral position, which was followed by Harken's implantation of prosthesis in aortic position²⁻⁴. Consequent to these landmark surgical feats, the prosthetic valve development has witnessed innumerable turning points namely,

Table 3 : Table showing Demographic characteristics of Study Population

PARAMETERS		PVT (n=10)	WIC (n=13)	AF-FVR (n=10)	ENDOCAR B.ABCESS (n=2)	STROKE (n=1)	OTHERS (n=9)
GENDER	Male	6 (60%)	6 (46%)	5 (50%)	0	1 (100%)	6 (67%)
	Female	4 (40%)	7 (54%)	5 (50%)	2 (100%)	0	3 (33%)
MEAN duration after Valve Replacement (IN YRS)		5.4	5.3	11.2	8	4	5.8
ANTICOAGULATION	YES	9	10	8	2	1	8
	NO	1	0	2	0	0	1
COMPLIANCE	YES	3	10	7	2	1	6
	NO	7	0	3	0	0	3
COMORBIDITIES (HTN, DM, IHD)		2	4	4	0	1	2
OLD CVE		1	0	2	1	0	1
PLACE OF ADMISSION	ICU	10	3	10	1	0	3
	WARD	0	10	0	1	1	6

PVT - prosthetic valve thrombosis, WIC - warfarin induced coagulopathy.

AF FVR - atrial fibrillation with fast ventricular rate

Table 4 : Symptoms in different complication

SYMPTOM	PVT n=10	WIC n=13	AF FVR n=10	ENDOCARD. B.ABCESS n=2	STROKE n=1	OTHERS n=9
BREATHLESSNESS	9 (90%)	0	3 (30%)	0	0	1
PALPITATION	0	2 (15%)	7 (70%)	0	0	1
BLEEDING MANIFESTATION	0	11 (85%)	0	0	0	0
FEVER	0	0	0	2	0	3
ALTERED SENSORIUM	1	1	0	1	0	1
OTHERS	0	1	0	0	0	3

Table 5 : Hemodynamic Profile of Patient Taken in Study

CLINICAL PARAMETERS	PVT n=10	WIC n=13	AF-FVR n=10	ENDOCARDITIS BRAIN ABCESS n=2	STROKE n=1	OTHERS n=9
TACHYCARDIA	10	4	10	2	1	5
HYPOXEMIA	7	0	0	0	0	2
RAISED JVP	10	0	4	0	0	1
SHOCK	6	3	0	0	0	2

Tachycardia = HR > 100, Hypoxemia = SPO₂ < 90 % on Room Air, Shock = MAP < 65 mmHg.

tilting discs designs in late 60s and bileaflet designs in late 70s; major preoccupations being the flow characteristics and durability of the prosthesis¹. However over the years the flip side of mechanical valve replacement, in the form of anticoagulant need

and its risks, has also surfaced significantly⁵. Such issues may not be glaring in developed countries with organized health care and homogenous literacy but in developing countries like India use and misuse of anticoagulant drug is a major cause of

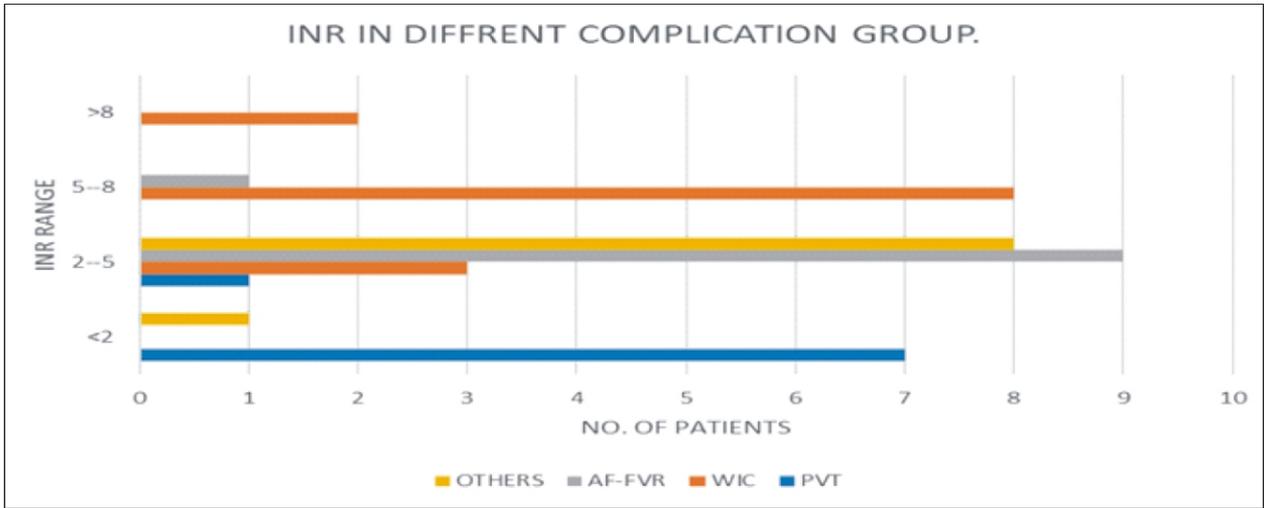


Fig. 2 : INR in Different Complication

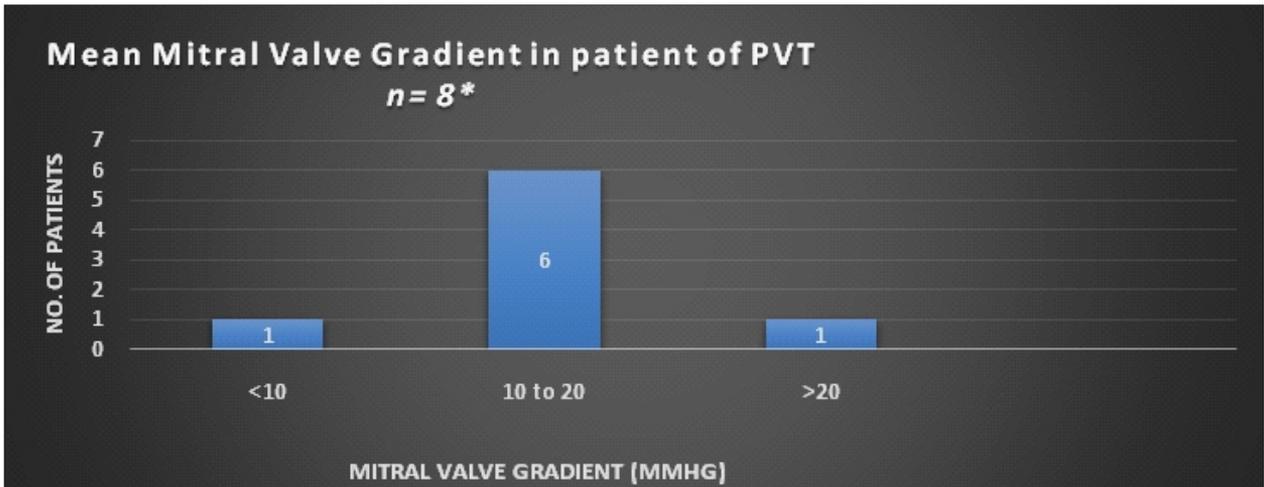


Fig. 3 : Mean Mitral Valve Gradient in Prosthetic Valve Thrombosis

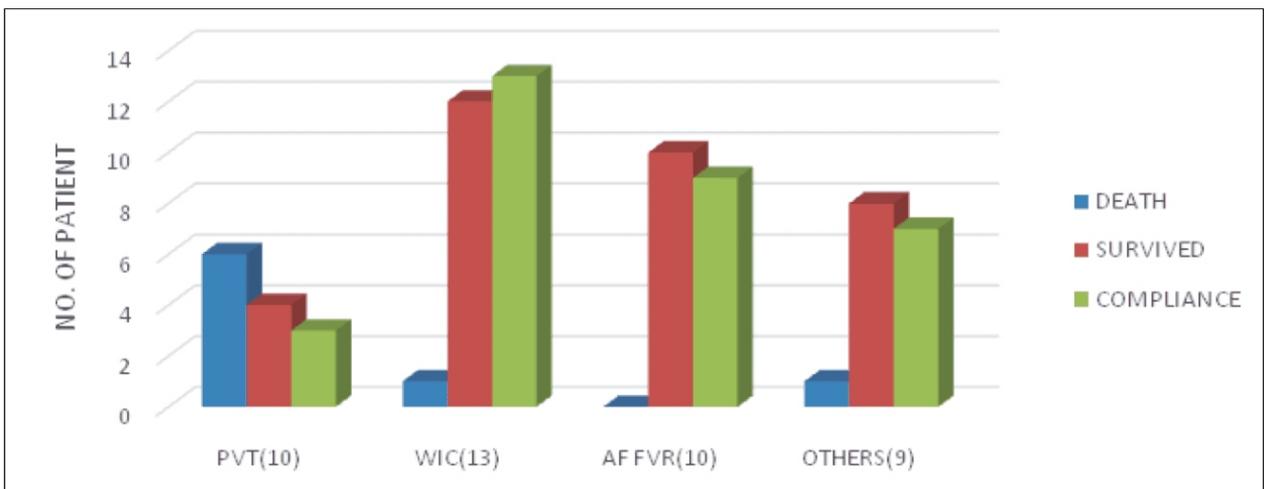


Fig. 4 : Mortality & Survival in Different Complications

concern^{6,7}. Our study was conducted to know magnitude of different complication in patient of prosthetic heart valve implantation. Prosthetic valve thrombosis is major concern after valve implantation as patient in country like India have no good healthcare facility especially in remote areas. The finding of our study was comparable to result of study carried out by **M Manjula et al⁸ & Buttard P, Bonnefoy E, Chevalier P, Marcaz PB, et al⁹**. Bleeding manifestation secondary to anticoagulants is also a significant complication observed in our study, not that lethal but was major cause of hospitalization with significant morbidity. And major reason for this was the lost to follow-up and taking medication without any monitoring. Al Hales from Saudi Arabia reported that only 25% of patients could be maintained in the therapeutic range of INR despite efforts to the contrary¹⁰. North et al have also noted that compliance is a major issue and biological valves imparted a survival advantage in their report¹¹. In view of illiteracy and poor follow up, coupled with ill developed health care structure, the current recommendation of ACC / AHA guidelines with reference to management of anticoagulation also has few practical implications in our setup¹²⁻¹³. As most of the population lack basic facility of prothrombin time estimation at their native place, patients have to travel for long distance to the hospital where they got operated, leading to non-compliance. If the patient's INR is off target it is desired to repeat INR within a week for optimizing the dose of anticoagulants, then the patient may have to stay near the hospital leading to loss of his livelihood. Most of the patients are illiterate and making them understand the need for regular blood test and anticoagulant intake is a difficult task. Prosthetic valve endocarditis is also a important complication of prosthetic heart valve implantation as shown by a study **Andrew Wang, Eugene Athan et al¹⁴**. Same result was present in our study but only few patients presented with endocarditis.

Stroke is a devastating complication that may occur early or late after operation in patients with prosthetic heart valves and result from embolism, intracranial haemorrhage, or both¹⁵. Although intracranial haemorrhage is a relatively rare event

except in elderly anticoagulated patients¹⁶⁻¹⁸, an embolic stroke may occur in virtually any patient and with any type of valve prosthesis. Stroke risk are more with mitral prosthesis as compared to aortic, due to high flow rate in aortic root. However in our study only one case presented with stroke who had mitral valve prosthesis. Patient was diabetic and taking anticoagulants with good compliance.

Atrial fibrillation is not a complication of prosthetic heart valve per se; but it was the major cause of repeated admission in ICU in patients with prosthetic valves.

Other causes for admission observed in study are not the complications of prosthetic heart valve; but these cardiac patients may be more susceptible than normal population to diseases and require care and proper followup.

Some complication like primary valve failure, pannus formation, valve fracture were not observed in study, may be due to short sample size or improved quality of valve material, also the mechanical valves implanted now a days have longer life.

Conclusion :

- 1) Prosthetic valve implantation is not free of complication. Post implantation care is an unmet need especially in remote areas.
- 2) Prosthetic valve thrombosis is the most important complication having significant mortality and can be prevented by good compliance of anticoagulants.
- 3) Anticoagulant Induced bleeding is common but less lethal complication and major cause of this complication is taking anticoagulant without having INR monitoring.
- 4) Atrial fibrillation is major cause of repeated admission in hospital in patients with heart valve prosthesis

Limitation :

- 1) Low sample size
- 2) Restricted facility for transoesophageal echocardiography.
- 3) Inadequate facility for reoperation in choked valve patients.

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