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Clinical Profile and Outcome after Thrombolysis of Prosthetic Valve Thrombosis

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Abstract: ***Background: the study was conducted to evaluate clinical profile and outcome after thrombolysis of prosthetic valve thrombosis. Methods: This was a prospective, observational, single-centre study carried out between January 2021 and December 2021 at a tertiary care centre in central India. Total 25 patients with history of symptoms related to PHVT were included in the study. Patients underwent thrombolysis as per clinical presentation. The demographic profile, clinical parameters and in hospital outcome were analysed. Results: Mean age of the patients was 42.3±14.1 years. Most of the patients presented with NYHA class III and IV (100%) symptoms. Of the total 25 patients studied 16 (64%) were poorly compliant with anticoagulants. All were thrombolysed with streptokinase. Mortality was found to be of 8 %. Embolism occurred in 24 % and major bleeding in 8 %. Conclusions: Majority of patients with prosthetic valve thrombosis presented with a subtherapeutic INR value, poor compliance and poor monitoring mainly in patients belonging to the lower socioeconomic group. Thrombolysis can be a useful option in the management of prosthetic valve thrombosis patients in a less resourceful country.***

Keywords: Prosthetic heart valve, Thrombosis, Streptokinase, Thrombolysis

1. Introduction

Prosthetic valve thrombosis leading to valvular obstruction is a life-threatening complication whose treatment remains controversial [1]. The incidence of mechanical prosthetic valve thrombosis varies across countries. It has an incidence of 0.6% to 6% in the left-sided valves and up to 20% In tricuspid valves [2].

In contrast to the Western countries, rheumatic valvular heart disease is the most commonly encountered valvular pathology in the developing countries. These valvular heart pathologies mostly require surgical replacement with prosthetic valves. There are a number of complications associated with mechanical prosthetic valves postoperatively.

Early diagnosis of mechanical prosthetic valve thrombosis followed by prompt treatment is important as delay in diagnosis and treatment can lead to increase morbidity and mortality [3]

Different factors predispose to mechanical prosthetic valve thrombosis leading to obstruction the most common being inadequate anticoagulation therapy followed by thrombotic states like atrial fibrillation, pregnancy and ventricular dysfunction [4].

These treatment options vary from patient to patient depending upon the prosthetic valve position, size of the thrombus and hemodynamic status of the patient. Intravenous anticoagulation is considered in cases of right-sided prosthetic valve thrombosis with low thrombus burden and in left-sided prosthetic valve thrombosis if the patient is hemodynamically stable [5].

The appropriate management of PHVT has been still debatable. Some guidelines (ESC) recommend surgery for all, irrespective of clinical status, while some (Society of Heart Valve Diseases) recommend thrombolytic therapy for all patients without contraindications. Till date, there has been no class I recommendation in any guideline for management of PHVT due to no randomized controlled trials. [6]

We aimed to evaluate the clinical profile and outcome after thrombolysis of Prosthetic valve thrombosis at tertiary care center in central India

2. Material and Methods

It was a prospective and interventional study conducted at tertiary care center of central India. The patients presenting with clinical suspicion of mechanical prosthetic valve thrombosis after mechanical valve replacement were included in the study. After informed consent had been sought, they were subjected to a tests like complete blood counts international normalized ratio (INR) levels, transthoracic echocardiogram and fluoroscopy

The patients who were diagnosed with mechanical prosthetic valve thrombosis and hemodynamic instability were treated with 250, 000 units of intravenous streptokinase bolus followed by infusion at the rate of 100, 000 units per hour for 12-24 hours after excluding the contraindications and serial echocardiography was done to assess the gradient across prosthetic valve.

The clinical outcomes were defined in terms of hospital deaths and complications related to thrombolysis.

Continuous variables were presented as mean ± standard deviation and categorical variables as counts and percentages. All data were analysed using the Statistical Package for Social Sciences (SPSS; Chicago, IL, USA) program, version 15. A p-value <0.05 was considered significant.

3. Results

A total of 25 patients with prosthetic valve thrombosis were identified and analyzed in this study. Mean age of the patients was 42.4±14.6 years. Majorities were in the age group between 31 to 45 years. Majority of the patients were females (17; 68%) [table no 1].

The predisposing factor leading to valve replacement was rheumatic heart disease in majority (76%) of the patients followed by congenital (12%) and degenerative (8%) [table no.2]

Almost all the patients presented with NYHA class III and IV (100%) symptoms [table no 3].

Majority of the patients (18; 72%) had an international normalised ratio (INR) in non-therapeutic range (<2). [Table no 4]. More patients in economically underprivileged groups had discontinued medications when compared to those who were a better socioeconomic group.

In all cases the decision to thrombolyse, was taken by considering the hemodynamic instability and functional class of each patient and with proper exclusion of contraindications. The treatment options were also discussed with the patients and their relatives about the risk of complications and benefits.

All patients were thrombolysed with streptokinase by standard dosing protocol of 250000 units intravenous stat dose followed by infusion of 100000 units per hour for 12-24 hours.

The duration of infusion was based on the clinical response and complications.

Of the total 25 patients studied 16 (64%) were non compliant of these 12 (75%) were females [table no.5]

Of the 25 patients who underwent thrombolysis, complete response was achieved in 92 % of the patients. Mortality in the thrombolysis was 8%. Embolism occurred in 24 % of the group and major bleeding was in 8 % [Table no 6]

The most common complication in the study group was embolism followed by bleeding manifestations. Most of the embolic manifestation resulted in a cerebro-vascular accident (CVA) followed by acute limb ischemia in 1; (4%)

Table 1: Age distribution of study subjects

Age in years	No. of patients	Male	Female
15 – 30	5	1	4
31 – 45	11	3	8
46 – 60	7	2	5
>60	2	2	0
Total	25	8	17
Mean Age SD (Range)	42.32+14.61	49.75 + 18.94	38.82 +11.08

Table 2: Etiology of Valve replacement

Etiology	Total
RHD	19 (76%)
Degenerative	2 (8%)
CHD	3 (12%)
ISCHEMIC	1 (4%)

Table 3: Symptoms class on presentation

NYHA Class	Total (25)
I	0
II	0
III	10 (40%)
IV	15 (60%)

Table 4: INR levels on admission

INR	Total
<2	18 (72%)
>2	7 (28%)

Table 5: Drug Compliance

	Total (25)	Males	Females
Good	9 (36%)	7 (77%)	2 (23%)
Poor	16 (64%)	4 (25%)	12 (75%)

Table 6: Association of Complications and outcome

Complication	Total (25)	Survivors (92%)	Non-Survivors (8%)
NO	17 (68%)	17	0
CVE (ISCHEMIC)	5 (20%)	5	0
CVE (BLEEDING)	2 (8%)	0	2
ALI	1 (4%)	1	0
SEPSIS	0	0	0

4. Discussion

Mechanical prosthetic valve thrombosis is a clinical emergency which is associated with high rates of morbidity and mortality.

Early diagnosis and appropriate management are paramount in reducing mortality due to such complication. We have studied total 25 patients of PHVT treated over a period of 12 months. In our study PHVT was more common in women (68%). Similarly many studies from India have shown that women have been more predisposed to PHVT [7].

In developed countries the incidence of PHVT is 0.3% to 6% found while in developing countries it is 10% to 12% [8, 9]. The main reason for this high incidence is the low socioeconomic and low education status of most of the patients, which results in poor compliance of oral anticoagulation therapy.

In our study, 72% of the patients had suboptimal INR and 64% having had poor compliance with oral anticoagulation therapy. Similar results were found in another study in which 55.50% of the patients had suboptimal INR [10]. The reason being female predominance of patients (58.50%) who are usually lost to follow-up after replacement resulting in suboptimal INR and poor compliance with warfarin

In a recent study by Karthikeyan G et al, 72% (79/110) of the patients had inadequate anticoagulation at presentation. [11] This highlights the problems of valve replacement in a developing country such as India where majority of the population is economically underprivileged.

Mortality in the study was 8%. Similarly, consensus statements on the treatment of PHVT and recent systematic reviews, suggest that the success rate with fibrinolytic therapy is at least 80% [11-12]. Moreover, Sharma and Mewada in a study on 48 patients used streptokinase and reported 81% success and 8% mortality [13]. Singh S et al, also used streptokinase in 44 patients with PHVT and reported 73% success and 6.8% mortality [14].

In this study embolism was occurred in 24% of patients. Other studies have shown an embolic risk of 12% to 17% caused by thrombolysis [15, 16].

5. Conclusion

Poor compliance with warfarin and subtherapeutic INR levels are the important factors causing mechanical prosthetic valve thrombosis, thus necessitating the need for patient education in the form of videos of stuck valve with its consequences and also about risk associated with second surgical operation. Fibrinolysis with streptokinase is a reasonable treatment option for mechanical prosthetic valve thrombosis.

The importance of continuing anticoagulants can be emphasised during every follow up visit.

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Ethical approval: The study was approved by the Institutional Ethics Committee

References

[1] Cevik C, Izgi C, Dechyapirom W, Nugent K: Treatment of prosthetic valve thrombosis: rationale for a prospective randomized clinical trial. J Heart Valve Dis.2010, 19: 161-170.
[2] Hermans H, Vanassche T, Herijgers P, Meuris B, Herregods MC, Van de Werf F, Verhamme P: Antithrombotic therapy in patients with heart valve prostheses. Cardiol Rev.2013, 21: 27-36.10.1097/CRD.0b013e3182638578
[3] Musumeci L, Jacques N, Hego A, Nchimi A, Lancellotti P, Oury C: Prosthetic aortic valves: challenges and solutions. Front Cardiovasc Med.2018, 5: 46.10.3389/fcvm.2018.00046
[4] Duran NE, Biteker M, Ozkan M: Treatment alternatives in mechanical valve thrombosis. (Article in Turkish). Turk Kardiyol Dern Ars.2008, 36: 420-425.
[5] Nagy A, Denes M, Lengyel M: Predictors of the outcome of thrombolytic therapy in prosthetic mitral valve thrombosis: a study of 62 events. J Heart Valve Dis.2009, 18: 268-275
[6] Krishnan S. Prosthetic heart valve thrombosis: Diagnosis and newer thrombolytic regimes. J Prac Cardiovas Sci.2016; 2 (1): 7.
[7] Reddy YS, Pingali K, Otikunta AN, Nathani S, Malladi SR. A study of indications, complications of prosthetic valves and prognosis after treatment of stuck valve. Blood pressure.2017; 100 (70): 80
[8] Biteker M, Altun I, Basaran O, Dogan V, Yildirim B, Ergun G: Treatment of prosthetic valve thrombosis: current evidence and future directions. J Clin Med Res.2015, 7: 932-936.10.14740/jocmr2392w
[9] Karthikeyan G, Math RS, Mathew N, et al.: Accelerated infusion of streptokinase for the treatment of left-sided prosthetic valve thrombosis: a randomized controlled trial. Circulation.2009, 120: 1108-1114.10.1161/CIRCULATIONAHA.109.876706
[10] Patil S, Setty N, Ramalingam R, Rudrappa MMB, Manjunath CN: Study of prosthetic heart valve thrombosis and outcomes after thrombolysis. Int J Res Med Sci.2019, 7: 1074-1078.
[11] Karthikeyan G, Math RS, Mathew N, Shankar B, Kalaivani M, Singh S, et al. Accelerated infusion of streptokinase for the treatment of left-sided prosthetic valve thrombosis: a randomized controlled trial. Circulation.2009; 120 (12): 1108-14.
[12] Reyes-Cerezo E, Jerjes-Sánchez C, Archondo-Arce T, García-Sosa A, Garza-Ruiz Á, Ramírez-Rivera A, et al. Fibrinolytic therapy in left side-prosthetic valve acute thrombosis. In depth systematic review. Archivos de cardiologia de Mexico.2008; 78 (3): 309-17.
[13] Cáceres-Lóriga FM, Pérez-López H, Santos-Gracia J, Morlans-Hernandez K. Prosthetic heart valve thrombosis: pathogenesis, diagnosis and management. Int J Cardiol.2006; 110 (1): 1-6
[14] Sharma KH, Mewada NM. Efficacy and safety of streptokinase in prosthetic valve thrombosis (total 5 years clinical registry). Indian J Pharmacol.2010; 42 (5): 330.
[15] Singh S, Doshi S, Salahuddin S, Tarik M, Barwad P, Ramakrishnan L, et al. Antistreptokinase antibodies and outcome of fibrinolytic therapy with streptokinase for left-sided prosthetic valve thrombosis. American Heart J.2015; 169 (1): 170-4.
[16] Asante-Korang A, Sreeram N, McKay R, Arnold R. Thrombolysis with tissue-type plasminogen activator following cardiac surgery in children. International J Cardiol.1992; 35 (3): 317-22.
[17] Witchitz S, Veyrat C, Moisson P, Scheinman N, Rozenstajn L. Fibrinolytic treatment of thrombus on prosthetic heart valves. Heart.1980; 44 (5): 545-54.