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Original article:

Thrombolytic treatment of prosthetic valve thrombosis: a single center study using Tenectiplase

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ABSTRACT:

Aims & Objectives: The aim of this study was to analysed the safety and effectiveness of medical management given in the form of thrombolytic therapy with tenectiplase in patients suffering from prosthetic valve thrombosis.

Methods: 40 patients of mechanical valve replacement came with stuck valve were given thrombolytic treatment using tenectiplase. A single dose of 40 mg of tenectiplase intravenous bolus injection was given and it was followed by anticoagulation with low molecular weight heparin daily. Patients kept admitted until the transvalvular pressure gradient was normal or close to normal. Transthoracic echocardiography (TTE) was used every 12 h to monitor whether the thrombus was reduced and whether there was haemodynamic improvement. Routine blood tests, the prothrombin time (PT), international normalized ratio (INR) and complications were observed every day.

Results: 72.5 % (29 out of 40 patients) patients were treated successfully with thrombolytic therapy. 20 % patients have shown partial improvement in symptoms. In three patients (7.5%) there were no improvement in symptoms. 2 patients develops intracranial haemorrhage leading to hemiplegia. There was no incidence of haemoptysis, haemetemesis and urinary bleeding. There was no incidence of anaphylaxis or death.

Conclusion: like other thrombolytic agents tenectiplase is also safe and effective in the treatment of prosthetic valve thrombosis. It would be more beneficial in patients those are high risk for redo surgery.

Key Words: stuck valve,Thrombolytic treatment, Prosthetic valve thrombosis, Transthoracic echocardiography

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Introduction

Rheumatic heart disease is the most common cause of valvular dysfunction in Indian population. Most commonly affected age group is between 5 and 15 years of age (1), so most of the patients become symptomatic in adulthood. Therefore mechanical valve replacement remains the most common operative intervention in cardiovascular surgery. Formation of thrombus over mechanical prosthetic valve is a life threatening complication and occur mostly in the patients who are poorly compliant with post- operative anticoagulant therapy. The data regarding incidence of prosthetic valve thrombosis is emerging(2-6). Presently thrombolysis and emergency surgery are the two primary modalities of treatment. In this retrospective study effectiveness and safety of thrombolytic agent tenectiplase is analysed.

Methods

From March 2020 to September 2020, total 40 patients of prosthetic valve thrombosis were admitted in cardiovascular and thoracic surgery department of Govind Ballabh Pant Hospital, New Delhi. Clinical symptoms, 2-D echocardiography and fluoroscopy were the main steps to make the diagnosis of prosthetic valve thrombosis. Clinically dyspnea (uaually of grade 3 /4), palpitation and weakness were the presenting complains. In thransthoracic 2-D echocardiography peak and mean transvalvular gradients and leaflet mobility of involved valve were assessed, and if any doubt diagnosis was confirmed by fluoroscopy. Transesophageal echocardiography was not done in every case because of lack of availability. After diagnosis, thrombolysis was the first choice of treatment in all cases.

Table 1. Detail of admitted patients

Total admitted patients	40
Male	22 (55 %)
Female	18 (45 %)
Average age	35+/- 10
Presenting symptoms	
1. Dyspnea (functional class iii-iv) 2. Palpitation 3. Easy fatigability	40(100 %) 32(80 %) 28(70%)

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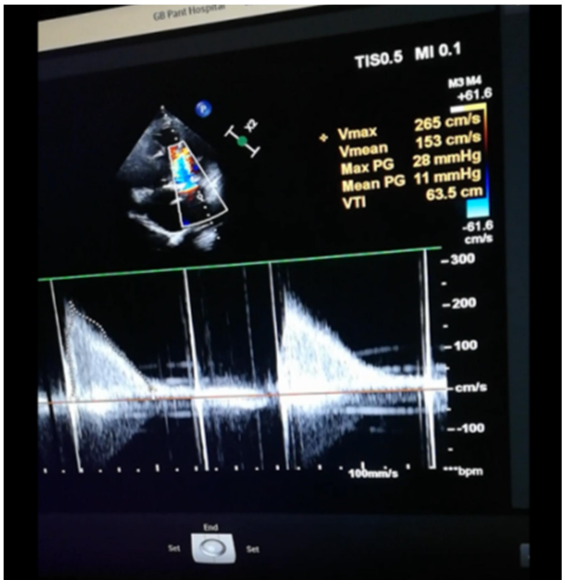

Figure 1. 2D Echocardiography image showing high mean and peak gradient across stuck mitral valve

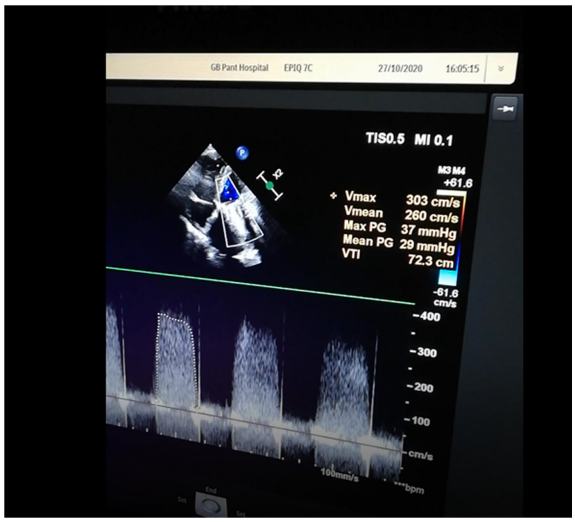

Figure 2. . 2D Echocardiography image showing high mean and peak gradient across stuck mitral valve

Thrombolytic therapy

The risks and benefits of both redo surgical valve replacement and thrombolytic therapy were discussed with each patient and their relatives.A informed written consent was taken from all the patients before thrombolytic therapy was started. All the confirmed cases of stuck valve were treated with thrombolytic agent regardless of the operating surgeon and type of valve used. A 40 mg single bolus dose of Tenectiplase was administered, followed by anticoagulation with low molecular weight heparin every day. Patients were followed until they get symptomatic relief and the transvalvular gradient was normal or near to normal. Fluoroscopy and transthoracic echocardiography

were repeated after 12 hours to assess the mobility of valve leaflets and reduction in transvalvular gradient. Changes in haemodynamic status including having symptomatic improvement, development of any complications were assessed every hourly. Routine blood tests including complete blood count, platelet count, prothrombin time and international normalization ratio were done daily.

Thrombolysis was considered completely successful when patients get complete relief in symptoms and transvalvular gradient came to normal along with movement of both leaflets of mechanical valve without any serious complication. Partial success was considered when patient get significant symptomatic improvement and near normal transvalvular gradient along with partial restriction in one leaflet mobility in absence of any bleeding complications. Thrombolytic therapy was considered failed when patient get no relief in symptoms, no change in valve activity or if develop any serious complication after thrombolysis.

Results

Effectiveness of thrombolytic therapy

Out of 40 patients, 29 (72.5%) were successfully treated with thrombolytic agent. Eight patients (20 %) get only partial relief in symptoms and three (7.5 %) patients didn't get any relief in symptoms. Out of 30 patients of mitral valve, 22(73.3 %) patients get treated successfully, 6 (20%) patients get partial improvement in symptoms and 2(6.66%) patients didn't get any improvement in symptoms. Out of the three patients of aortic valve, 2 (66.6%) patients get complete successful thrombolysis but one patient didn't get any improvement in symptoms or valve hemodynamics. Seven patients were of double valve mitral and aortic) replacement, in all these seven patients mitral valve was stuck and out of these 7 patients five get complete relief in symptoms and in two patients partial success was achieved. Three patients, one of stuck aortic valve and two of stuck mitral valve underwent redo surgery of valve and recovered successfully.

Dosage of Tenectiplase

In all the patients single bolus intravenous dose of 40 mg of Tenectiplase was given and this dose remain same same in all the patients. No repeat injection was given to any patient.

Safety of thrombolytic therapy

Embolic episode: one patient develops thromboembolic complications leading to right sided hemiplegia which improved gradually.

Bleeding complications: two patients develop haematuria which was treated conservatively. Ovarall mortality was 2.5% (1/40) where patient came in pulmonary edema and shock.

Follow-ups

All the patients were explained about the level of improvement which was achieved on valve leaflet mobility and cross-valve gradient. Patients ware again explained about the timing and dosage of anticoagulant treatment. In follow-up period 2-D echocardiography and if needed fluoroscopy were advised on OPD basis.

Table 2. Results

Total admitted patients	40
Mitral valve replacement	30
Aortic valve replacement	03
Double (mitral and aortic) valve replacement	07
Success rate	
Complete success rate	29(72.5%)
Partial success rate	08(20%)
No improvement in symptoms	03(7.5%)
Number of patients underwent reoperation	03(7.5%)
Complications	
Thromboembolic episodes	01
Haematuria	02

Discussion

In present scenario bileaflet mechanical valves are the prosthetic valve of choice. Thrombosis of these valves is very serious complication and only limited data is available regarding the treatment of choice in these patients. The treatment options includes thrombolytic therapy, emergency surgery followed by intensive anticoagulation therapy. Treatment options depends on factors such as patients clinical condition, available treatment options, economic condition of the patient and experience and availability of redo surgery infrastructure. The role of transesophageal echocardiography for diagnosing the size,site and characterstics of thrombus has been emphasized by Dvavik V,Cohen G et al.(7) Various studies have been done worldwide to assess the outcomes of thrombolytic therapy on left-sided prosthetic valve thrombosis. Silber H, Khan S S reported that thrombolytic therapy can be used as the first line of therapy for thrombosed St. Jude valves with a low risk of permanent side effects and excellent chances of success. In most cases, surgery can be reserved for patients who do not respond to thrombolytic therapy (8). In a meta-analysis of observational studies which were done to compare the outcome of urgent surgery with fibrinolytic therapy for the treatment of left-sided prosthetic heart valve thrombosis Karthikeyan G concluded that urgent surgery was not superior to fibrinolytic therapy at restoring valve function, but substantially reduced the occurrence of thrombo-embolic events, major bleeding, and recurrent PVT. In experienced centers, urgent surgery should probably be preferred over fibrinolytic therapy for treating left-sided PVT(9). In the developing countries like ours

where there are economic constraints regarding surgical cost and limited availability of hospitals experienced in reoperations made the thrombolytic therapy the first treatment modality. Many thrombolytic agents used such as Reteplase, urokinase, streptokinase, recombinant plasminogen activator has been used in thrombosis. Streptokinase was the most commonly used fibrinolytic agent (used in 44%), followed by t-PA in 38% of cases(9). In this retrospective study tenectiplase was used for thrombolysis. Complete success was achieved by 72.5 % of patients and 20 % of the patients get partial improvement in symptoms. All the patients included in this study either were poorly compliant with anticoagulant treatment or lost follow-up. The major complication of this therapy are bleeding tendencies, thromboembolic events. In bleeding complications haematuria was reported by two patients and one patient develop ischemic cerebrovascular accident. No other major bleeding incident was noted in this study.

Conclusion

Tenectiplase used in this study is found effective and safe thrombolytic agent. This therapy is used in both left sided valve thrombosis and the results in this study shows that tenectiplase is sefe and effective. Another alternative that is emergency surgery has limited availability and is chosen by the patients where thrombolytic therapy didn't provide significant outcome.

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Ethics approval: approval from departmental ethical committee obtained.

Consent: Consent for participation and publication of data for research purpose was obtained from patients.

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