Comparison of Fibrinolytic versus Surgical Therapy in the Treatment of Obstructive Prosthetic Valve Thrombosis:
A Single-Center Experience

Necip Ermis, MD,1 Hakan Atalay, MD,2 Hakan Altay, MD,3 Muhammet Bilgi, MD,1 Suleyman Binici, MD,1 Alpay T. Sezgin, MD3

1Cardiology Department, Inonu University, Turgut Ozal Medical Center, Malatya; Departments of 2Cardiovascular Surgery and 3Cardiology, Baskent University, Medical School, Adana, Turkey

ABSTRACT

Objective: Prosthetic heart valve thrombosis (PVT) is a rare but severe cardiac condition. There are only a few data regarding comparison of the fibrinolytic and surgical approaches for the treatment of PVT. In this study, we compared the results of fibrinolytic therapy versus surgery in patients who presented to our institution with a diagnosis of obstructive-type PVT.

Methods: From January 2001 to August 2008 in our institution, 33 patients who met clinical and echocardiographic criteria for obstructive-type PVT were included in the study. Fifteen of these patients underwent fibrinolytic treatment with streptokinase, which consisted of an initial bolus of 250,000 U followed by 100,000 U/h. Eighteen patients were treated with surgery.

Results: The 2 groups had similar baseline characteristics, including New York Heart Association functional status, types and positions of prosthetic valves, international normalized ratio values, and presentation symptoms. Full hemodynamic success was achieved in 12 patients who underwent fibrinolytic therapy and in 15 patients in the surgery group. The mean (±SD) streptokinase infusion time was 17.8 ± 11.1 hours. Two major hemorrhages and 2 cases of systemic embolism were observed in the fibrinolytic group. The 2 groups did not differ with respect to mortality rate (P = .79). The duration of hospitalization was longer in the fibrinolytic group than in the surgery group (10.7 ± 6.6 days versus 6.9 ± 6.7 days, P = .045).

Conclusions: Although fibrinolytic therapy is generally recommended for the treatment of PVT for specific patient groups, our results suggest that it may be as efficacious and safe as surgery, depending on patient selection.

INTRODUCTION

Prosthetic heart valve thrombosis (PVT) is a complication attributable to any type of thrombus attached to a mechanical prosthetic valve that causes dysfunctional hemodynamics or systemic embolization [Edmunds 1996]. Recent-onset dyspnea, fatigue, or other signs of systemic embolization are clinical findings of PVT. It is a rare but life-threatening condition, depending on its generation and biocompatibilities, the location of the prosthesis valve, and the adequacy of anticoagulation therapy [Edmunds 1982; Thorburn 1983; Kontos 1989]. Although surgery is the traditional treatment option, surgical mortality rates range from 4.7% in low-risk groups to 37% to 54% in high-risk groups [Husebye 1983; Deville 1987; Montero 1989; Deviri 1991; Martinek 1991; Roudaut 2003b; Durrleman 2004].

Beginning with the first report in 1971 regarding the application of fibrinolytic therapy for a thrombus stuck on a tricuspid valve [Luluaga 1971], more than 500 left-side prosthetic valve thrombi have been successfully treated with fibrinolytic therapy as an alternative to surgery [Reddy 1994; Agrawal 1997; Gupta 2000; Ozkan 2000; Kumar 2001; Lengyel 2001; López 2002; Roudaut 2003a; Tong 2004; Lengyel 2005; Cáceres-Lóriga 2006a]. Although the success rate of fibrinolytic therapy for treating PVT is 77% to 90%, it is also associated with mortality, embolism, and bleeding risk (2.5%-11.8%, 4%-15%, and 2.9%-8.3%, respectively).

Currently, there are only a few data regarding comparison of the fibrinolytic and surgical approaches for the treatment of PVT [Lengyel 2001; Azpitarte 2001]. Therefore, our aim was to compare the results of fibrinolytic therapy versus surgery in patients who presented to our institution with a diagnosis of obstructive-type PVT.

METHODS

Patients

From January 2001 to August 2008 in our institution, 33 patients who met the clinical and echocardiographic criteria for obstructive-type PVT were included in the study. The patients’ symptoms, times of symptom onset, New York Heart Association (NYHA) functional capacities, and findings of systemic embolization were recorded. In addition, we also recorded the types of anticoagulants and antiplatelet...
agents used, international normalized ratio (INR) values, and heart rhythm data at admission. Data regarding implantation, type, size, and position of the prosthetic heart valves were also obtained from the hospital registries. Over the last 7 years in our institution, 18 patients with PVT were treated with surgery, and 15 patients underwent fibrinolytic therapy. The treatment strategy was based on the presence of comorbid conditions, the physician’s preferences, and the availability of cardiac surgery at the time.

**Diagnosis**

Depending on the clinical suspicion, PVT was confirmed with transthoracic echocardiography and fluoroscopic examinations. All patients later underwent transesophageal echocardiographic (TEE) examination by an experienced echocardiographer for a detailed investigation and to plan the treatment strategy. The efficacy of fibrinolytic treatment was evaluated by a TEE evaluation repeated 24 hours after the completion of fibrinolytic therapy. The criteria for successful thrombolysis were TEE-documented disappearance of thrombus, normalization of leaflet mobility, and normalization of the transvalvular gradient and prosthetic valve area.

**Fibrinolytic Therapy**

Only streptokinase therapy with a 30-minute loading dose of 250,000 U followed by 100,000 U/h was used as fibrinolytic therapy. Streptokinase infusion was continued until a completely successful response was obtained; otherwise, streptokinase infusion was lengthened up to 48 hours. Patients with a bleeding tendency, hemorrhagic cerebral infarcts, large thrombus burdens at the prosthetic valve, or thrombosis in the left atrium did not undergo fibrinolytic therapy. Intravenous heparin infusion was discontinued during fibrinolytic therapy. Following successful fibrinolytic therapy, heparin and warfarin therapies were restarted; heparin infusion was continued until an INR value >2.5 was achieved.

**Surgery**

Surgery was performed as the first-line therapy in 18 patients. The operative procedure was either valve re-replacement with a mechanical valve in 15 patients and declotting/pannus excision in 3 patients.

**Complications**

Major bleeding was defined as necessitating blood transfusion or a decrease in the blood hemoglobin concentration of >2 mg/dL. Detailed neurologic and cerebral computed tomographic examinations were performed if neurologic symptoms occurred during or after fibrinolytic therapy.

**Statistical Analysis**

Statistical analysis was performed with SPSS for Windows (version 11.0; SPSS, Chicago, IL, USA). Continuous variables were expressed as the mean ± SD. Differences between groups for continuous variables were tested with the Student t test for unpaired data after normality was demonstrated. Otherwise, a nonparametric test (Mann-Whitney U test) was used. Between-group differences in categorical factors were compared with the chi-square test or the Fisher exact test, when appropriate. Logistic regression models were used to construct a multivariate model for predicting mortality. A stepwise selection technique was used to identify factors for the final multivariate model. A P value <.05 were considered statistically significant.

**RESULTS**

The baseline characteristics of the patients are summarized in Table 1. In both groups, the main clinical signs at the time of presentation were dyspnea, angina, cerebrovascular accident, and shock. There were no significant differences between the fibrinolytic therapy and surgery groups with respect to baseline characteristics, except for the time between symptom onset and diagnosis, which was significantly longer in the surgery group (Table 1).
Efficacy of Fibrinolytic Therapy

Values for baseline and posttreatment hemodynamic parameters for the patients in the fibrinolytic therapy group are presented in Table 2. The mean (±SD) streptokinase infusion time was 17.8 ± 11.1 hours. Two major hemorrhages and 2 cases of systemic embolism were observed in the fibrinolytic therapy group. There was no difference between the 2 groups with respect to the mortality rate (P = .79). The duration of hospitalization was longer in the fibrinolytic therapy group than in the surgery group (10.7 ± 6.6 days versus 6.9 ± 6.7 days, P = .045). Full fibrinolytic success was achieved in 12 cases (80%). One patient with tricuspid valve thrombus did not respond to fibrinolytic therapy and was successfully treated with surgery. Failure of fibrinolytic treatment was observed in 2 patients with a monoleaflet prosthetic valve and in 1 patient with a bileaflet prosthetic valve.

Safety of Fibrinolytic Treatment

Overall, hemorrhagic complications were observed in 4 patients. Two of these cases involved major bleeding: one patient with a subdural hemorrhage who was successfully treated with surgery and the other with a gastrointestinal hemorrhage successfully treated medically. Systemic embolism was observed in 2 patients (stroke and coronary emboli). These patients were in NYHA classes III and IV at baseline; they did not respond to fibrinolytic therapy and died. Logistic regression analysis revealed no independent association between complications and such variables as age, sex, systolic blood pressure, heart rate, baseline INR value, NYHA functional class, history of stroke, and thrombotic valve type. During 3.7 ± 2.1 years of follow-up, rethrombosis was observed in 1 patient who was treated successfully with streptokinase.

Efficacy and Safety of Surgery

An uneventful hospital course was achieved in 14 patients (Table 3). A cerebral embolus observed in 1 patient led to partial disability. Three patients in NYHA functional class IV died from low cardiac output syndrome. Two of these patients had bileaflet prostheses, and the third had a monoleaflet prosthesis, all in the mitral position. Logistic regression analysis revealed that only NYHA functional class was associated with mortality (P = .04; odds ratio, 2.2). There was no association between death and such variables as age, sex, systolic blood pressure, heart rate, baseline INR value, and thrombotic valve type.

The mean duration of hospitalization in the surgery group was 6.9 ± 6.7 days. During 3.5 ± 1.7 years of follow-up, rethrombosis of the prosthetic heart valve was observed in 1 patient; this patient died before other therapy could be applied.

Comparison of the Efficacies for the 2 Treatment Strategies

There were no significant differences between the 2 treatment strategies regarding the incidence of death and stroke (Table 4). The rethrombosis rates for prosthetic heart valves also were not different. The duration of hospitalization was longer in the fibrinolytic therapy group than in the surgery group (10.7 ± 6.6 days versus 6.9 ± 6.7 days; P = .045). A longer duration of hospitalization in the fibrinolytic therapy

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Table 2. Prosthetic Heart Valve Type and Position with Hemodynamic Measurements at Baseline and after Thrombolytic Treatment in the Thrombolytic Group

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Valve Type and Position</th>
<th>Mean Gradient at Baseline, mm Hg</th>
<th>Mean Gradient after Thrombolytic Treatment, mm Hg</th>
<th>Total Thrombolytic Time, h</th>
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<tr>
<td>1</td>
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<td>7.4</td>
<td>20</td>
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<tr>
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<tr>
<td>3</td>
<td>Mitral, MT, MO</td>
<td>6</td>
<td>5.4</td>
<td>14</td>
</tr>
<tr>
<td>4†</td>
<td>Aortic, MT, MO</td>
<td>86</td>
<td>—</td>
<td>2</td>
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<tr>
<td>5</td>
<td>Mitral, ATS, BL</td>
<td>11</td>
<td>5</td>
<td>24</td>
</tr>
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<td>26</td>
<td>6.8</td>
<td>14</td>
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<tr>
<td>7</td>
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<td>24</td>
<td>24</td>
<td>48</td>
</tr>
<tr>
<td>8</td>
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<td>25</td>
<td>6.2</td>
<td>14</td>
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<td>9</td>
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<td>16</td>
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<tr>
<td>15†</td>
<td>Mitral, SO, BL</td>
<td>14</td>
<td>—</td>
<td>10</td>
</tr>
</tbody>
</table>

*SJ indicates St. Jude Medical; BL, bileaflet; MT, Medtronic Hall; MO, monoleaflet; ATS, Medtronic ATS Medical; CM, CarboMedics; SO, Sorin.
†Patient died.
The presence of atrial fibrillation, a history of ischemic stroke, and a large mobile thrombus visible with TEE are predictors of complications during fibrinolysis treatment [Gupta 2000; Tong 2004]. In our study, thrombolytic therapy was preferred if the patient had comorbidities (an advanced age or additional disorders that make surgery very high risk, such as chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, decompensated cardiac failure, chronic renal failure, chronic obstructive lung disease, 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heart failure, systemic and other disorders, and so forth). It was also used in patients for whom surgery was otherwise the first choice but who had to undergo fibrinolytic therapy because they were critically ill and a surgical team was unavailable at the time. Additionally, if the echocardiographic appearance of the thrombus (TEE evidence of a small soft mass without accompanying left atrial thrombus) convinced the physician that the patient might benefit from thrombolytic therapy, thrombolytic therapy was preferred to surgery. In the multicenter PRO-TEE study, a thrombus size of 20.8 cm² according to TEE imaging was found to be a significant predictive factor for systemic embolism, irrespective of NYHA functional class [Tong 2004]. Therefore, measurement of thrombus size by TEE is recommended for risk stratification in the management of PVT. In our cases, although we did not measure the thrombus burden in every patient, the presence of a large mobile thrombus on the prosthetic heart valve and a coexisting left atrial thrombus were accepted as contraindications for fibrinolysis because of the higher embolization risk [Ozkan 2000; Tong 2004]. NYHA functional class has not been accepted in most studies as a predictor for complications and/or success for fibrinolysis, whereas it is an important factor in the surgical treatment of prosthetic valve endocarditis [Ozkan 2000; Tong 2004]. Our results were also in agreement with these reports. Rethrombosis of prosthetic heart valves after fibrinolytic therapy (frequency range, 11.1%-27.8%) may be another problem, and success rates for retreatment with fibrinolysis range from 70% to 91% [Reddy 1994; Gupta 2000; Ozkan 2000; Kumar 2001; Lengyel 2001; Roudaut 2003a; Cáceres-Lóriga 2006a]. In our study, rerecurrent thrombosis occurred in 1 patient after fibrinolytic therapy, and it was successfully treated with repeat fibrinolytic therapy.

There are limited data regarding the comparison of outcomes after fibrinolytic therapy versus surgical therapy for the treatment of PVT. Azpitarte et al [2001] reported complete success with fibrinolytic treatment in 19 PVT patients, whereas 5 of 14 patients died in the surgery group. In a registry of 59 patients with prosthetic valve endocarditis, Lengyel and Vandor [2001] reported high success and low mortality rates with fibrinolysis (84.4% and 6.2%, respectively), compared with the success and mortality rates after surgery (66.7% and 33.3%, respectively). In that study, fibrinolysis was shown to be superior to surgery for obstructive PVT, especially for patients in NYHA class IV. Although these 2 small studies indicated higher success rates with fibrinolysis than with surgical therapy, we observed the 2 groups to have similar success and complication rates. The accumulating evidence suggests that surgery should be considered, especially in patients with an accompanying left atrial thrombus, active bleeding, a history of intracranial bleeding, or any evidence of ischemic stroke within the previous 4 hours to 6 weeks or during the early postoperative period after valve replacement [Cevik 2010].

**Limitations**

The small sample size and the retrospective design are the main limitations of our study. In addition, the selection criteria for fibrinolysis therapy were based on the clinical judgment of the physicians and the availability of a cardiac surgery team.

**CONCLUSION**

Although fibrinolytic therapy is generally applied to critically ill patients with comorbidities, severely impaired cardiac function, and right-sided PVT, our results suggest that fibrinolytic therapy may be as efficacious and safe as surgery, depending on patient selection. In selected cases, this treatment strategy could be preferred, owing to low complication and high success rates. Therefore, the treatment strategy for PVT should be individualized; however, further large-scale studies and experience are needed to clearly define the best therapeutic option.

**REFERENCES**


