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# St. Jude Medical Valve in Pulmonary Position: Anticoagulation and Thrombosis



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## ABSTRACT

Between 1979 and 1985, 5 patients underwent pulmonary valve replacement with a St. Jude Medical valve. During follow-up ranging from 30 months to 18 years, there were 6 episodes of valve thrombosis in 4 patients. Three episodes were treated by thrombolysis. Reoperation was necessary in 3 patients. Although the St. Jude Medical valve in the pulmonary position can occasionally function long-term without anticoagulation, these cases show the high risk of thrombosis and need for anticoagulation.

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## INTRODUCTION

Pulmonary valve replacement (PVR) to eliminate pulmonary insufficiency subsequent to complete repair of cyanotic heart defects, particularly tetralogy of Fallot, improves right ventricular (RV) function in selected cases with RV failure.<sup>1</sup> The use of mechanical valves in the pulmonary position has largely been abandoned because of a high incidence of clotting complications.<sup>2–4</sup> However, questions remain regarding anticoagulation and treatment of valve thrombosis in patients with a mechanical pulmonary prosthesis already in place. A review of the cardiac surgery database at our institute revealed 5 patients had undergone PVR with a St. Jude Medical (SJM) valve (St. Jude Medical Inc., St. Paul, MN, USA). The operations were carried out between October 1979 and June 1985. During that time, there were no other types of valve implanted or procedures performed to eliminate pulmonary insufficiency. All patients had undergone previous cardiac repairs at 7 days to 13 years of age. Patient characteristics are summarized in Table 1.

## CASE REPORTS

### CASE 1

A patient with tetralogy of Fallot and absent pulmonary valve underwent primary repair at the age of 10 years. Progressive RV failure developed due to severe pulmonary insufficiency, so PVR with a 23-mm SJM valve was performed 10 years later. The patient did well without anticoagulation for 18 years, but then developed thrombosis as evidenced by exertional dyspnea and substernal chest discomfort. The SJM valve was replaced with a pulmonary homograft. Intraoperatively, extensive pannus as well as fresh thrombus were found around the valve and on both support struts, totally immobilizing one valve leaflet and partially immobilizing the second. After a further 18 years of follow-up, the patient was doing well with no thromboembolic complication.

### CASE 2

A patient with a primum atrial septal defect, mitral and tricuspid insufficiency, and pulmonary stenosis underwent

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repair at 7 years of age. A Hancock valved Dacron conduit (Medtronic Inc., Minneapolis, MN, USA) was placed between the right ventricle and pulmonary arteries because of the tricuspid insufficiency. Obstruction of the Dacron conduit developed 5 years later, so the conduit was removed, right ventricle-to-pulmonary artery continuity was reestablished, and a 21-mm SJM valve was placed in the pulmonary position. The patient was maintained without anticoagulation for 9 years before starting warfarin treatment. The SJM valve has remained functional during 17 years of follow-up.

CASE 3

A 3-year-old patient with tetralogy of Fallot underwent primary repair including placement of an autologous pericardial transannular patch. Five years later, PVR was carried out with a 23-mm SJM valve because of RV failure and pulmonary insufficiency. The patient was maintained without anticoagulation but developed thrombosis and underwent thrombolytic treatment 8 months later. Warfarin therapy was started after thrombolysis. There has been no recurrence of thrombosis in 14 years of follow-up.

CASE 4

A 14-year-old patient with tetralogy of Fallot and no previous palliation, underwent primary repair including placement of a transannular autologous pericardial patch. Three years later, aneurysmal dilatation of the RV outflow tract developed and PVR was carried out with a 23-mm SJM valve. No anticoagulant was given in the first 6 years, then warfarin was started. However, the patient was noncompliant with the anticoagulation and subsequently suffered 3 episodes of valve thrombosis and one pulmonary embolism; the first episode was 9 years after PVR. Following 2 successful thrombolytic treatments, the patient underwent reoperation after the 3rd episode, and the SJM valve was replaced with a pulmonary homograft. Intraoperatively, extensive pannus was found around the valve, with a partially immobilizing thrombus on the leaflets. The patient has been doing well without any thromboembolic complication for 14 years after the homograft replacement.

CASE 5

A patient with tetralogy of Fallot and pulmonary atresia underwent palliative RV outflow tract reconstruction with an autologous pericardial patch, in the neonatal period. Ventricular septal defect closure and PVR with a 19-mm SJM valve prosthesis was performed at the age of 20 months, and the patient was maintained without anticoagulation. Thrombosis developed 2.5 years later and the SJM valve was replaced with a Carpentier-Edwards bioprosthesis (Baxter Healthcare Corp., Santa Ana, CA, USA). Intraoperatively, there was a small amount of thrombotic material on the hinge points of the valve. The patient was followed up for 2.5 years, but has not been in contact for the last 3 years.

Table 1. Patient Profile and Outcome

Case	Diagnosis	Initial Operation	Age at PVR (years)	Valve Size (mm)	Anti-Clotting Regimen	Thrombosis	1st Thrombosis (years)	Streptokinase Thrombolysis	Reoperation	Follow-up (years)
1	TOF + absent PV	TOF repair	20	23	Aspirin	1	18	0	Homograft	18
2	ASD + PS	ASD closure + valved conduit	12	21	Aspirin + warfarin after 9 years	0	-	-	-	17
3	TOF	TOF repair	8	23	Aspirin + warfarin after 9 months	1	0.7	1	-	14
4	TOF	TOF repair	17	23	Aspirin + warfarin after 6 years	3	9	2	Homograft	12
5	TOF + PA	RVOT reconstruction	1.7	19	Aspirin	1	2.5	-	Bioprosthesis	2.5

ASD = atrial septal defect, PA = pulmonary artery, PS = pulmonary stenosis, PV = pulmonary valve, PVR = pulmonary valve replacement, RVOT = right ventricular outflow tract, TOF = tetralogy of Fallot.

## DISCUSSION

Anticoagulant or antiplatelet therapies alone or in combination can prevent clotting complications with mechanical valves. The hazards of anticoagulation and problems of dosage control in a child must be weighed against the possibility of thrombosis. Pass and colleagues<sup>5</sup> suggested not using warfarin after right-sided SJM valve replacement. However, anticoagulation after PVR with a mechanical prosthesis has been widely used since follow-up data showed high thrombosis rates.<sup>2,3</sup> In our patients, valve thrombosis occurred on antiplatelet therapy and warfarin.

Thrombosis of mechanical valves (MVs) in the pulmonary position usually progresses slowly. Because pulmonary insufficiency or pulmonary stenosis caused by MV dysfunction is usually well tolerated compared to left-sided valve thrombosis, many patients are asymptomatic.<sup>2-4</sup> The higher incidence of thrombosis of SJM valve prostheses in the pulmonary position compared to those on the left side, suggests a difference in coagulation conditions. This may be due to variations in the pressure difference and turbulent flow to which a sewing collar and adjacent endocardium are exposed. Two approaches can be applied in the management of thrombosed MVs in the pulmonary position: thrombolytic treatment or surgical removal. Successful thrombolysis has been demonstrated in patients with MV thrombosis when there is no accompanying pannus formation.<sup>4,6,7</sup> Avoidance of the risks of reoperation is the major advantage of thrombolytic treatment, but it has its own risks and limitations. These include bleeding, embolization, and need for subsequent anticoagulation to guard against rethrombosis. Moreover, thrombolysis fails in 15% to 30% of cases, usually due to obstruction of the valve by pannus rather than thrombus. An analysis of 26 cases of thrombolysis for thrombosed right-sided MVs reported over the last decade has revealed a primary success rate of approximately 70% and an early rethrombosis rate of 10%.<sup>8</sup> Rethrombosis after thrombolysis is related to the duration of thrombosis and the presence of concomitant fibrous tissue on the valve. One of our patients did well after thrombolysis whereas another needed redo PVR after 2 successful thrombolytic treatments. No bleeding or embolization occurred at the time of thrombolysis. Replacement of a thrombosed MV with a homograft or a bioprosthetic valve is another option with low operative risk, good long-term results, and freedom from anticoagulation. Both of our patients did well after homograft

replacement, without a thromboembolic event. An alternative approach, given large central and branch pulmonary arteries and low pulmonary vascular resistance, is removal of the MV without replacement.

Similar to previous reports, our data show a high risk of thrombosis and need for anticoagulation, although the SJM valve in the pulmonary position may occasionally function long-term without anticoagulation. These cases also indicate that fibrinolytic treatment may be reasonable for a first thrombotic episode. However, the surgical approach which is effective with low operative risk, good long-term results, and freedom from anticoagulation is advisable in patients who develop recurrent thrombosis.

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