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Original Article

Feasibility and Complications of the St. Jude Medical Mechanical Heart Valve- A Brief Study

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Abstract

Background: *The St. Jude Medical bileaflet mechanical valve was designed by Xinion (Chris) Posis and Donald Hanson who came up with the concept of a leaflet-tab rotating in a "butterfly recess" in the inner wall of the housing with the hinge mechanism located near the central axis of the housing. The bileaflet configuration provided central, evenly distributed flow patterns with small areas of flow separation, minimal flow resistance, low profile, large effective orifice area, and ease of surgical implantation. The valve leaflets and housing were made of pyrolitic carbon and the sewing cuff of double velour dacron. The valve satisfies many of the features of an ideal valve such as long-term durability, non thrombogenicity and hemodynamic efficiency. However, its clinical dependence on chronic anticoagulation persists.*

Methods: *Between January 2003 to December 2014, 430 patients were studied who had undergone or underwent mitral valve, aortic valve or double valve (both aortic and mitral) replacement with the St. Jude Medical bileaflet valve.*

Results: *A total of 430 cases were studied. The mean age of operation was 39.16± 9.7 years. The operative mortality rate was 5.5% overall. The average period of follow-up was 4.21± 3.2 years. Structural valve deterioration was not seen in any patient in the series. Nonstructural valve dysfunction was reported in 7 patients. Clinically significant hemolysis was not seen in any patient. Thromboembolism was reported in 22 patients. Valve thrombosis was reported in 3 patients. Major bleeding events requiring hospitalization or transfusion were reported in 17 patients. PVE was reported in 4 patients. There were 36 late deaths. 21 patients died of valve related causes, 9 from cardiac causes and 6 patients from non-cardiac causes. Overall survival rate was 90.66%.*

Conclusions: *Even though the St. Jude Medical bileaflet mechanical valve satisfies most of the features of an excellent mechanical valve substitute, the late valve related complications (especially thromboembolism and bleeding) and mortality, although low, illustrate that our quest for a "perfect" prosthesis remains.*

Keywords: *St. Jude valve, Mechanical valve, Morbididty, Mortality.*

Introduction

In October 1952, Dr. Charles Hufnagel implanted a caged ball valve in the descending thoracic aorta in a patient with aortic valve disease. The valve consisted of a methacrylate ball contained in a methacrylate tube[1].The development of St. Jude Medical bileaflet valve was facilitated by Mr Manny Villafana, founder of Cardiac Pacemakers Inc[2]. The design of the valve was developed by Xinion (Chris) Posis, an industrial engineer who developed a prototype of a bileaflet valve with the pivots near the periphery and a central opening. Subsequently, Mr Villafana and his engineers determined that this was not a workable design. Posis then redesigned the valve with another engineer, Donald Hanson who came up with the concept of a leaflet-tab rotating in a "butterfly recess" in the inner wall of the housing with the hinge mechanism located near the central axis of the housing. The final design features of the St. Jude Medical valve defined its simplicity and functionality[3]. The bileaflet configuration provided central, evenly distributed flow patterns with small areas of flow separation, minimal flow resistance, low profile, large effective orifice area, and ease of surgical implantation. The highly polished, silicon- alloyed pyrolytic carbon material used for both the orifice and leaflets provided maximum thromboresistance, durability, and wear resistance. The controlled dimensional clearances between the orifice and leaflets provided complete washing of all exposed surfaces, minimal hemolysis, limited regurgitation, and free leaflet motion. The seamless, double-velour Dacron sewing cuff provided rapid and controlled tissue ingrowth and minimal thrombosis and thromboembolism. The optimally spaced and positioned pivot locations provided full, stable, responsive leaflet opening and closing and minimal leaflet exposure. The orifice butterfly and leaflet ear pivot geometries permitted "free floating" leaflet rotation and retention without the use of hinge pins or struts and full 85-degree opening and 30 to 35-degree closing.

In summary, the valve satisfies many of the features of an ideal valve[4] such as long-term durability, non thrombogenicity and hemodynamic efficiency. However, its clinical dependence on chronic anticoagulation persists.

Methods

The study was carried out in the Department of CVTS at Sher-i-Kashmir Institute of Medical Sciences. It was a prospective and a retrospective study. The study period was from January 2003 to December 2014.

Inclusion Criteria

- Patients who underwent valve replacement with the St. Jude Medical bileaflet mechanical valve in the aortic (AVR), mitral (MVR) or in both (DVR, aortic and mitral) positions.
- Patients who underwent AVR, MVR or DVR with the St. Jude Medical bileaflet valve along with an additional procedure which included CABG, tricuspid valve repair, aortic root enlargement for small aortic valve.
- Patients who underwent AVR with repair of mitral valve or MVR with repair of aortic valve.

Exclusion Criteria

- Patients who underwent AVR, MVR or DVR with St Jude Medical bileaflet valve along with tricuspid valve replacemnet.
- Patients who underwent AVR or MVR along with aortic root replacement (Bentall procedure)
- Patients with severe LV dysfunction (ejection fraction < 35%) who underwent AVR or MVR with St. Jude Medical bileaflet valve.
- Patients with LA or LV thrombus.
- Patients who underwent emergency MVR with St. Jude Medical bileaflet valve and CABG in patients with acute ischemic mitral regurgitation.
- Patients who underwent valve replacement with St. Jude Medical bileaflet mechanical valve with severe comorbidity preoperatively

which included severe COPD, renal failure, etc.

Hospital survivors were followed up monthly for first six months after surgery, then every two months up to one year, then every three months in the second year. From third year onwards, the follow up was every six months. In addition to blood chemistry tests, echocardiographic evaluation including Doppler studies was routinely done for all patients during the follow up. Also, once a month, an INR was done to evaluate the level of anticoagulation. The dose of warfarin was adjusted accordingly.

If a patient reported any adverse event, it was recorded. The patient was managed according to protocol followed by the concerned department.

Follow up ended in December 2014.

Standard guidelines to define hospital and late mortality and valve-related events were followed according to the guidelines of The Society of Thoracic Surgeons and the American Association for Thoracic Surgery[5].

Statistical Methods

Values are reported as the mean ± 1 standard deviation. Actuarial curves were constructed to describe mortality and the incidence of valve-related complications. Individual event-free curves were calculated for valve-related mortality and overall mortality, as well as for the incidence of reoperation, endocarditis, thromboembolic events, and anticoagulant-related hemorrhage. Valve-related deaths were given precedence over nonfatal complications in cases in which both occurred. Actuarial estimates were calculated by the Kaplan-Meier technique.

A total of 430 cases were studied. The mean age of operation was 39.16± 9.7 years. 199 (46.27 %) patients were males and 231 (53.72 %) patients were females. Aortic valve replacement (AVR) alone was done in 98 patients (22.8%). mitral valve replacement (MVR) was done in 229 patients (53.2%). Combined aortic and mitral valve replacement (DVR) was done in 103 patients (24%). The operative mortality rate was 5.5% overall. Sepsis was the cause in majority of patients (n= 15). Twenty one patients (5.2%) could not be located and were considered lost to follow-up. Therefore 94.8% (384) patients were included in this study. The average period of follow-up was 4.21± 3.2 years. Structural valve deterioration was not seen in any patient in the series. Nonstructural valve dysfunction was reported in 7 patients- six patients had a paravalvular leak and one patient had prosthetic valve dysfunction due to in growth of pannus. Clinically significant hemolysis was not seen in any patient. The incidence of nonstructural valve deterioration was 0.4/ 100 patient years of follow up. The freedom from nonstructural valve deterioration was 98.2% overall.

Thromboembolism was reported in 22 patients. The incidence of thromboembolism was 1.35/ 100 patient years of follow up. The freedom from thromboembolism was 94.3% overall. Valve thrombosis was reported in 3 patients. The incidence of valve thrombosis was 0.18/ 100 patient years of follow up. The freedom from valve thrombosis was 99.2% overall. Major bleeding events requiring hospitalization or transfusion were reported in 17 patients. The incidence of bleeding complications was 1.05/ 100 patient years of follow up. The freedom from bleeding complications was 95.6% overall. PVE was reported in 4 patients. All the cases of PVE were reported in the first three years of operation. The incidence of PVE was 0.2/ 100 patient years of follow up. The freedom from PVE was 99% overall. Reoperation was reported in 4 patients. The cause of reoperation was perivalvular dehiscence in 2 patients, valve thrombosis in one patient and infective endocarditis in one patient. The reoperation rate was 0.2/ 100 patient years of follow up. The freedom from reoperation was 99 % overall. There were 36 late deaths. 21 patients died of valve related causes, 9 from cardiac causes and 6 patients from non-cardiac causes. Overall survival rate was 90.66%.

Discussion

The St. Jude Medical bileaflet valve is one of the best performing mechanical prosthesis currently available. The central-flow, pyrolytic carbon, bileaflet, mechanical heart valve represents a simple yet highly functional valve design whose excellent clinical performance since 1977 attests to its clinical elegance. Both in vitro and in vivo studies demonstrated low gradients across the valve in both catheter-ization and echocardiographic evaluations. The valve satisfies many of the features of an ideal valve such as long-term durability, non thrombogenicity and hemodynamic efficiency. The current study reports our long-term experience with this valve.

The early mortality rate in our series was 5.5% overall. Our overall operative mortality rate is not significantly different from that reported in other series[6-11]. Sepsis was the predominant cause of mortality in the early years of our study. This was due to the fact that there was no separate Cardiac ICU for cardiac surgical patients. There was only a single intensive care unit in which critically ill patients were kept along with cardiac surgical patients. As a result cross infections were common with resultant ventilator associated pneumonia and wound infections being a common phenomenon. Ever since the creation of a separate cardiac surgical ICU, the incidence of infections has reduced drastically and sepsis as a cause of death is less frequently reported. Another common cause of death during the early years of study was bleeding diathesis. This was due to long cross clamp time due to the learning curve of the surgeon and unavailability of ACT machine to monitor the response to standard heparin dose. As a result, reexplorations and transfusion of multiple blood products were common. With improvement in the learning curve of the surgeons leading to shorter cross clamp times and the availability of ACT machine to monitor heparin effect, bleeding diathesis and reexplorations are now a rare phenomenon.

Structural valve deterioration was not seen in any patient in our series. Although occasional reports of structural failure of the St. Jude Medical valve have appeared, these incidents have been extremely rare. Fernandez et al reported one case of damaged leaflet which was attributed to rough handling before or during the operation. The defect was noticed after insertion of an aortic prosthesis. The valve was immediately replaced. Examination of the valve by the manufacturer showed surface scratches on the leaflet and an intact carbon coating by scanning electron microscopy[9]. Emery et al, in their series reported one patient who had early structural valve failure of valve implanted in the mitral position[10]. Embolization of one leaflet was the result of a manufacturing flaw, not prosthetic material wear. Reoperation was required. The fact that no structural failure occurred demonstrates the excellent durability of the St. Jude Medical valve, as compared with that of porcine and pericardial xenografts or earlier mechanical valves.

Nonstructural valve dysfunction includes clinically significant hemolysis, paravalvular leak without apparent endocarditis, entrapment by pannus, interference of valve function by suture and other causes. Clinically significant hemolysis was not seen in any patient in our series. Mechanical hemolysis related to prosthetic valves may be generally influenced by the extent of paravalvular leaks, valve orientation, asynchronous movements of leaflets, and leakage flow through a prosthetic valve[11]. Although paravalvular leaks have clearly caused significant hemolysis in patients with the St. Jude Medical valve in several series, not all cases of hemolysis have necessarily resulted from paravalvular leaks and not all cases of paravalvular leaks cause significant hemoysis (as in our series). In our experience, the orientation of the St. Jude Medical valve in the mitral position seems to be one of the important factors influencing hemolysis. When placed in the anatomical position, trace or mild regurgitant jet through the aortic valve collides against the anterior leaflet of the St Jude Medical valve that is perpendicular to the direction of the jet. This causes destruction of red blood cells.

This observation is supported by the fact that significant hemolysis is not seen in patients with AVR alone. In our study, in all patients undergoing MVR, the St Jude Medical valves were implanted in an antianatomic orientation. In several series (Aayogi et al[8], Remadi et al[12]), clinically significant hemolysis was seen in the initial part of the study when the St Jude Medical valve was implanted in the antanatomical orientation in the mitral position. In the later part of their study, no clinically significant hemolysis was seen when the mitral prosthesis was implanted in the antanatomical orientation.

Thromboembolism remains a major complication after mechanical valve replacement. The linearized rate of thromboembolic complications in this series was 1.35% patient year. The incidence of thromboembolism is comparable with other series of St Jude Medical mechanical valve replacement(0.8% to 3.5%/patient-year) [6, 13-15]Hemodynamic characteristics of blood flow across the St. Jude Medical valve and the structural characteristics of the St. Jude Medical valve are considered to be the main reason for its low thrombogenicity. Because of its low thrombogenicity, some have suggested that postoperative anticoagulant therapy was not necessary for patients who received the St. Jude Medical valve, whereas Chaux and colleagues[16] and Baudet and associates[17] have shown that without the administration of anticoagulants the incidence of valve thrombosis and systemic embolism was significantly higher and that a low incidence of thromboembolism could be achieved only when anticoagulants were administered. As with the patients treated by Arom and colleagues[18] and others[16], all of our patients received oral anticoagulant therapy with warfarin.

Major bleeding events requiring hospitalization or transfusion were reported in 17 patients. The incidence of bleeding complications was 1.05% patient years. This represents a considerable low rate of anticoagulant-related bleeding. In general, keeping in consideration the low rate of thromboembolism of the St Jude Medical mechanical prosthesis, we have gradually lowered our target INR from 2.5 to 3.5 to 2.0 to 2.5 as have other groups[19, 20], and this may have accounted for the low rate of bleeding complications. Overall, however, thromboembolic and bleeding complications continue to be the Achilles' heel of mechanical valve replacement, accounting for most of the valve-related morbidity seen in these patients.

The incidence of prosthetic valve endocarditis was quitelow (0.2% patient years) and is similar to other series.[10,21,22]. This complication, however, carried a substantial mortality in this study (50%) despite aggressive medical and surgical intervention. It is interesting to note that after 5 years, there is complete freedom from endocarditis in the aortic, mitral and double valve replacement groups. Ithas been speculated that valve design, increased probabilityof prosthetic valve sterilization, and early incorporation ofthe cloth sewing ring by tissue in growth may offer some protection from late bacterial invasion. Because prosthetic valve endocarditis is an extremely serious complication in patients who receive prosthetic valves, prophylaxis of infection with various invasive procedures, including dental and genitourinary procedures, is important.

In summary, the incidence of valve-related complications and deaths in patients implanted with the St. Jude Mechanical bileaflet valve is extremely low, with no incidence of structural valve failure. Even though the St. Jude Medical bileaflet mechanical valve satisfies most of the features of an excellent mechanical valve substitute, the late valve related complications (especially thromboembolism and bleeding) and mortality, although low, illustrate that our quest for a "perfect" prosthesis remains.

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