Prosthetic Cardiac Valve Replacement "CardiaMed": Evaluation of Short-term Outcome

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Abstract

Objectives: To determine short-term outcome of valve replacement (VR) using CardiaMed valve.

Patients & Methods: The study included 39 patients; 19 patients were assigned for aortic VR and 20 patients for mitral VR. All patients underwent clinical status rating using New York Heart Association (NYHA) classification and echocardiographic data collected preoperatively and at the end of follow-up. Operative and postoperative (PO) details and valve-related complications were defined. Thirty-days PO and late mortality were determined. Patients' satisfaction with the surgical outcome was graded using a 5-point scoring system.

Results: Immediate PO complications included cardiac rhythm related complications in 11 patients, infectious complications in 9, high-serum creatinine in 3 and para-valvular leak (PVL) in 3 patients. Two patients developed endocarditis, but one patient deteriorated and died on the 18th PO day. Another patient developed massive gastric bleeding during the 5th PO month and died on the next day. At the end of 20 months follow-up, the frequency of patients among NYHA classes and its mean value were significantly improved compared to preoperative frequency. Patients had AVR showed significant improvement of estimated Echo parameters in comparison to preoperative data, while patients had MVR showed significantly improved pressure gradient, however, other parameters were non-significantly different. Twenty-five patients were satisfied, 11 patients found results are good and only 2 patients found the outcome poor with non-significant difference between patients had AVR and MVR.

Conclusion: Cardiamed prosthetic VR is safe and effective for functional and echocardiographic improvement and provided satisfactory short-term outcome.

Keywords: Cardiamed prosthetic valve, Valve replacement surgery, Functional outcome, Patients' satisfaction.

Introduction

Both mechanical and bioprosthetic heart valves have become more durable and less thrombogenic, possessing excellent clinical outcomes and hemodynamic features. However, lifelong anticoagulant therapy is inevitable for patients with mechanical prosthetic valves, and those with bioprosthetic valves have higher risks of structural valve dysfunction than those with mechanical ones. In mechanical valves, bileaflet prosthetic heart valves are more preferably implanted than tilting disc valves, and surgeons choose some of them for valve replacement according to their own preference and the patients' informed consent [1, 2, 3].

Many long-term clinical results showed excellent clinical performances of mechanical prostheses. Mechanical prosthetic heart valves have an extremely low rate of structural failure and, with proper anticoagulation, the risk of thromboembolism is similar to the use of bioprosthetic ones without anticoagulants. Therefore, mechanical prostheses would be the choice for patients with longer life expectancy and no contraindication for anticoagulation [4, 5, 6].

Cardiamed valve, a prosthesis that was designed to be free from the shortcomings intrinsic to the valves like St. Jude Medical prosthesis. The housing and leaflets of the Cardiamed valve are made from solid isotropic pyrolytic carbon. Due to uniqueness of the technology for production of the solid pyrolytic carbon, which is unavailable to the other current world manufacturers of heart valve prostheses, the material has unique properties with respect to its strength and reliability [7, 8].

Comparison of the main characteristics for both types of material used for heart valve applications included specific weight; both types of material have the same specific weight about 2.1 g/cm^3, hardness; both types of material have sufficient hardness above 1000 Mpa, isotropy; both types of material are isotropic, but in contrast to the coated material, the degree of isotropy for the solid material is not just validated but is inspected for each workpiece in order to be sure of isotropic properties of the material, anisotropic inclusions due to fluctuations in the manufacturing processes could occur in both types of material, control over this phenomenon in the coated material is done by validation process which is incapable to provide complete assurance. The absence of anisotropic inclusions in the solid material is verified for each workpiece. Strength; the solid material is 1.5 stronger than the coated material [7, 8].

The current prospective study aimed to determine the short-term outcome of valve replacement using CardiaMed valve.

Patients & Methods

The current prospective study was conducted at Cardiosurgery departments, Benha University Hospital and Naser Institute since Jan 2011 till Feb 2012 to allow a minimum follow-up period of 12 months for the last case operated upon. All patients assigned for single valve replacement, either aortic or mitral were included in the study. Exclusion criteria included end-stage cardiac failure, irreversible major organ failure or terminal cancer with expected survival for <12 months, cerebro-vascular disease or neurological deterioration, active endocarditis, sepsis or active infection at time of implantation, any previous prosthetic valve replacement, multiple valve disease, emergency cardiac surgery.

All patients underwent preoperative full history taking and clinical examination, and laboratory investigations. Clinical status was rated using the New York Heart Association (NYHA) classification and echocardiographic data were collected preoperatively and at the end of follow-up.

All patients were operated with cardiopulmonary bypass (CPB) under moderate hypothermia (32–34^{o}C). A cold hyperkalemic crystalloid solution was used for myocardial protection. Postoperatively all patients were admitted to the intensive care unit (ICU). Anticoagulation therapy was initiated on the first postoperative (PO) day with heparin administration (5000 units subcutaneously, every 8 hours in order to achieve a partial thromboplastin time (PTT) between 60 and 80s. Oral intake of cumarin was started concurrently with heparin on the 1st PO day if possible. The target International Normalized Ratio (INR) was 2 to 2.5 for aortic valve replacement (AVR) and 2.5 to 3.5 for mitral valve replacement (MVR). Follow-up for anticoagulant monitoring was scheduled at time of discharge from the hospital and monthly or bimonthly postoperatively. For patients with atrial fibrillation who have mechanical valves, an INR of at least 2.5 is recommended, but for aged patients with some risk factors for cerebral bleeding, an INR is below 2.5 [9].

Perioperative mortality was defined as death occurring within 30 days of cardiac surgery, or death prior to hospital discharge regardless of cause. Late

mortality was defined as mortality after 30 days of cardiac surgery and hospital discharge. The cause of death was classified as being non-cardiac, cardiac but of a valve related cause (due to valve related complications) or cardiac of a non-valve related cause (heart failure, myocardial infarction, arrhythmia, sudden death). The valve related complications were defined according to the guidelines for reporting mortality and morbidity after cardiac valve interventions as hemorrhage, thrombo-embolism, prosthetic valve endocarditis, device thrombosis, structural valve deterioration and non-structural dysfunction including paravalvular leak [10, 11, 12, 13].

Patients' satisfaction with the surgical outcome was graded at end of follow-up using a 5-point scoring system with 4: highly satisfactory, 3: satisfactory, 2: good, 1: poor and 0: unsatisfactory.

Statistical analysis

Obtained data were presented as mean±SD, ranges, numbers and ratios. Results were analyzed using Wilcoxon; ranked test for unrelated data (Z-test) and Chi-square test (X^2 test). Statistical analysis was conducted using the SPSS (Version 15, 2006) for Windows statistical package. P value <0.05 was considered statistically significant.

Results

The study included 39 patients; 17 males and 22 females with mean age of 43.4±10.7; range: 24-56 years. Sixteen patients were obese, 15 patients were overweight and 8 patients had average BMI, with a mean total BMI of 29±3.3; range: 21-34.5 $kg.m^2$. Seven patients were smokers, 5 patients were Ex-smokers and 27 patients were never smokers. Twenty-one patients had associated co-morbidities in varied combinations, (Table 1).

Nineteen patients were assigned for AVR; 10 for aortic regurgitation, 5 for aortic stenosis and 4 for combined lesion. Twenty patients were assigned for MVR; 8 for mitral regurgitation, 5 for mitral stenosis and 7 for combined lesion. As regards etiology of valve disease; 17 patients had rheumatic valve disease, 8 patients had degenerative valve disease, 5 patients had endocarditis-related valvular disease, 4 patients had bicuspid aortic valve and 2 patients had aortic valve anuloectasia. Concerning the frequency of disease-related morbidities; 11 patients had previous cardiac surgery, 13 patients had atrial fibrillation, 8 patients were maintained on anticoagulant therapy and 9 patients had SPAP ≥50 mmHg. Twenty-one patients were of functional status III, 7 patients were of functional status II, another 7 patients were of functional status IV and 4 patients were of functional status III, (Table 2).

Mean aortic ischemia time was 54.9±5.5; range: 45-65 minutes; 10 patients were exposed to ischemia for <50 minutes, 21 patients for 50-60 minutes and 8 patients for >60 minutes. Mean CPB time was 86.8±13.7; range: 60-110 minutes and mean total operative time was 176.2±1.4; range: 130-220 minutes, (Table 3).

All patients passed surgery uneventful without intraoperative complications or mortalities. Five patients (12.8%) required mechanical ventilation for more than 24 hours, mean ICU stay was 2.9±1.1; range: 1-5 days and mean total hospital stay was 6.7±2.5; range: 3-14 days. Fourteen patients developed cardiac rhythm related complications; 11 developed arrhythmia and 3 developed ventricular fibrillation, however all cases were controllable. One patient developed pneumothorax and required drainage till complete resolution within 4 days after surgery. Nine patients had varied infectious complications. One patient developed transient ischemic attack and three patients had serum creatinine >1 mg/dl. Three patients developed para-

valvular leak (PVL), but fortunately it was mild leak that did not require re-operation and was followed conservatively, (Table 4).

Throughout the first 30-day, two patients had mitral valve replacement developed prosthetic valve endocarditis, both were followed conservatively, but unfortunately, one patient showed deterioration and developed a stroke on the 13th day after surgery and died on the 18th PO day. Another patient developed massive gastrointestinal bleeding during the 5th PO month, but unfortunately he was away from the hospital and badly managed at home and died on the second day of development of the bleeding attack. All survivors attended the hospital for follow-up for a mean duration of follow-up of 20.1±2; range: 16-24 months. Throughout the follow-up period, no valve-related complications were reported.

Functional outcome as determined by evaluation of NYHA class showed significant improvement at the end of follow-up period, both as the frequency of patients among classes and as a mean total value of the classes. The higher improvement reported in patients had mitral valve replacement compared to those had aortic valve replacement could be attributed to the higher frequency of mitral valve patients among low-function classes preoperatively, (Table 5, Fig. 1).

Echocardiographic data of patients had AVR determined at end of follow-up showed significant ($p<0.05$) improvement of estimated parameters in comparison to preoperative data. On contrary, MVR significantly ($p<0.05$) improved pressure gradient across the valve, however, other parameters showed non-significant ($p>0.05$) improvement in comparison to preoperative data, (Table 6).

Eleven patients showed high satisfaction; 14 patients were satisfied, 11 patients found results are good and only 2 patients found the outcome poor. There was non-significant ($p>0.05$) difference between patients had AVR and MVR as regards mean satisfaction score and frequency of patients among score strata, (Table 7, Fig. 2).

Table (1): Patients' enrollment data

Data				Findings
Age (years)	Strata	<30		7 (18%)
		30-40		8 (20.5%)
		>40-50		11 (28.2%)
		>50		13 (33.3%)
	Total			43.4±10.7 (24-56)
Gender	Male			17 (43.6%)
	Female			22 (56.4%)
Anthropometric data	Weight (kg)			84.2±9.7 (63-95)
	Height (cm)			170.3±3.6 (161-178)
	BMI (kg/m^2)	Strata	<25	8 (20.5%)
			25-30	15 (38.5%)
			>30	16 (20.5%)
		Total		29±3.3 (21-34.5)
Smoking	Non-smokers			27 (69.2%)
	Ex-smokers			5 (12.8%)
	Still smokers			7 (18%)
Associated co-morbidities	Arterial hypertension			13 (33.3%)
	Peripheral vascular disease			2 (5.1%)
	Diabetes mellitus			4 (10.3%)
	Renal dysfunction			1 (2.6%)
	Dyslipidemia			4 (10.3%)
	Endocarditis			5 (12.8%)

Data are presented as mean±SD & numbers; ranges & percentages in parenthesis; BMI: body mass index

Table (2): Patients' preoperative clinical data

		AVR	MVR	Total
Diseased valve status	Stenosis	10 (52.6%)	5 (25%)	15 (38.4%)
	Regurgitation	4 (21.1%)	8 (40%)	12 (30.8%)
	Combined disease	5 (26.3%)	7 (35%)	12 (30.8%)
	Total	19 (48.7%)	20 (51.3%)	39 (100%)
Etiology of valve disease	Rheumatic	4 (21.1%)	13 (65%)	17 (43.6%)
	Degenerative	5 (26.3%)	3 (15%)	8 (20.5%)
	Endocarditis	3 (15.8%)	2 (10%)	5 (12.8%)
	Myxametous	1 (5.3%)	1 (5%)	2 (5.1%)
	Bicuspide	4 (21.1%)	0	4 (10.2%)
	Anuloectasia	2 (10.5%)	0	2 (5.1%)
Disease-related morbidities	Previous valve surgery	3 (15.8%)	8 (40%)	11 (28.2%)
	Atrial fibrillation	2 (10.5%)	11 (55%)	13 (33.3%)
	Anticoagulation	1 (5.3%)	7 (35%)	8 (20.5%)
	SPAP (≥50 mmHg)	1 (5.3%)	8 (40%)	9 (23.1%)
NYHA class	I	3 (15.8%)	1 (5%)	4 (10.2%)
	II	4 (21.1%)	3 (15%)	7 (18%)
	III	9 (47.3%)	12 (60%)	21 (53.8%)
	IV	3 (15.8%)	4 (20%)	7 (18%)
	Mean±SD	2.63±0.96	2.95±0.76	2.79±0.86
EF (%)	<35	3 (15.8%)	2 (10%)	5 (12.8%)
	>35-45	2 (10.5%)	1 (5%)	3 (7.7%)
	>45-55	5 (26.3%)	7 (35%)	12 (30.8%)
	>55-65	6 (31.6%)	7 (35%)	13 (33.3%)
	>60	3 (15.8%)	3 (15%)	6 (15.4%)
	mean±SD	53.9±10.8	55.7±10.4	54.7±11.1

Data are presented as mean±SD & numbers; ranges & percentages in parenthesis; SPAP: systolic pulmonary artery pressure; NYHA: New York Heart Association; EJ: ejection fraction.

Table (3): Patients' operative data

Data		Findings
Aortic ischemia time (min)	<50	10 (25.6%)
	50-60	21 (53.8%)
	>60	8 (20.8%)
	Total	54.9±5.5 (45-65)
CPB time (min)		86.8±13.7 (60-110)
Operative time (min)		176.2±19.4 (130-220)

Data are presented as mean±SD & numbers; ranges & percentages in parenthesis; CPB: cardiopulmonary bypass

Table (4): Patients' immediate postoperative data

Data			Findings
Mechanical ventilation >24 hr			5 (12.8%)
ICU stay (days)			2.9±1.1 (1-5)
Total hospital stay (days)			6.7±2.5 (3-14)
Mortalities			0
Postoperative complications	Cardiac complications	Arrhythmia	11 (28.2%)
		Ventricular fibrillation	3 (7.7%)
	Pneumothorax		1 (2.6%)
	Infectious complications	Endocarditis	2 (5.2%)
		Superficial wound infection	2 (5.2%)
		Chest infection	2 (5.2%)
		Urinary tract infection	3 (7.7%)
		Total	9 (23.1%)
	Neurological complications		1 (2.6%)
	Renal insufficiency (serum creatinine> 1mg/dl)		3 (7.7%)

	Para-valvular leak	3 (7.7%)

Data are presented as mean±SD & numbers; ranges & percentages in parenthesis.

Table (5): Patients' NYHA data determined at end of follow-up in comparison to preoperative data

		Preoperative (n=39)			End of follow-up (n=37)		
		AVR	MVR	Total	AVR	MVR	Total
I		3 (15.8%)	1 (5%)	4 (10.2%)	8 (44.4%)	5 (26.3%)	13 (35.1%)
II		4 (21.1%)	3 (15%)	7 (18%)	9 (50%)	12 (63.2%)	21 (56.8%)
III		9 (47.3%)	12 (60%)	21 (53.8%)	1 (5.6%)	2 (10.5%)	3 (8.1%)
IV		3 (15.8%)	4 (20%)	7 (18%)	0	0	0
Sig.	X^2=				31.404	66.430	43.249
	p				<0.001	<0.001	<0.001
Mean±SD		2.63±0.96	2.95±0.76	2.79±0.86	1.61±0.6	1.84±0.6	1.73±0.6
Sig.	Z				3.819	4.185	5.652
	p				<0.001	<0.001	<0.001

Data are presented as mean±SD & numbers; ranges & percentages in parenthesis. Sig.: significance; p: significance versus preoperative data

Table (6): Patients' Echocardiographic data determined at end of follow-up in comparison to preoperative data

			Pressure gradient (mmHg)	EF (%)	EDV (ml)	ESV (ml)	LVPWD (cm)
AVR	Preoperative		43.5±12.7	56.8±9	172.1±28.7	74.4±10.2	1.4±0.28
	End of follow-up		12.3±4.4	62.4±4.9	142.8±30.9	46.9±11.8	1.17±0.19
	Sig.	Z	3.725	2.366	2.819	3.660	2.729
		p	<0.001	=0.018	=0.005	<0.001	=0.006
MVR	Preoperative		16.5±1.9	56.5±12.3	146.4±17.4	58.4±12.6	1.03±0.15
	End of follow-up		7.9±0.9	58.6±8.5	137.9±10.8	56.5±7.6	0.96±0.27
	Sig.	Z	3.825	1.604	1.772	0.521	0.830
		p	<0.001	>0.05	>0.05	>0.05	>0.05

Data are presented as mean±SD; ranges are in parenthesis. Sig.: significance; p: significance versus preoperative data; AVR: aortic valve replacement; MVR: mitral valve replacement; EF: ejection fraction; EDV: end-diastolic volume; ESV: end-systolic volume; LVPWD: Left ventricle posterior wall dimension

Table (7): Patients' satisfaction scoring determined at end of follow-up

		AVR	MVR	Total
Score	1	1 (5.6%)	1 (5.3%)	2 (5.4%)
	2	5 (27.8%)	6 (31.6%)	11 (29.7%)
	3	6 (33.3%)	7 (36.8%)	13 (35.2%)
	4	6 (33.3%)	5 (26.3%)	11 (29.7%)
Mean		2.94±0.94	2.84±0.9	2.89±0.9

Data are presented as mean±SD & numbers; ranges & percentages in parenthesis.

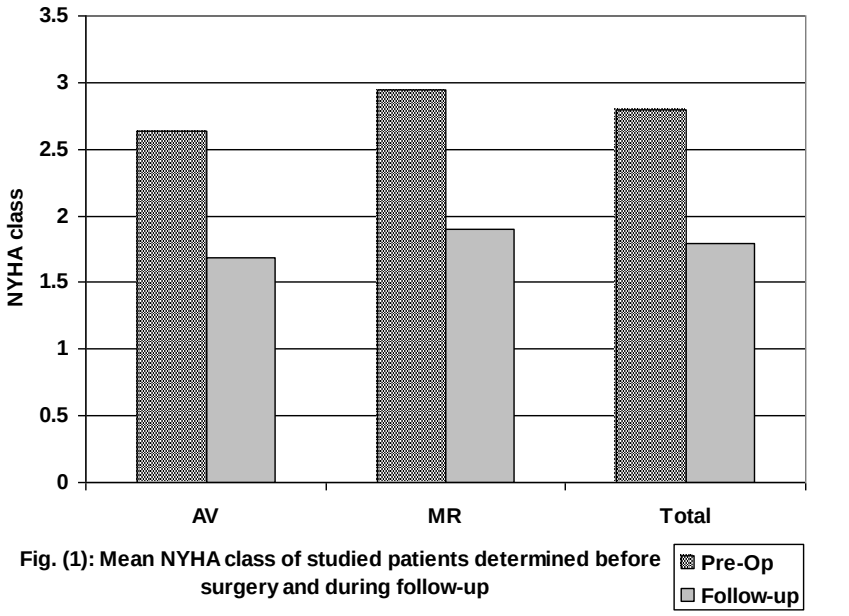

Fig. (1): Mean NYHA class of studied patients determined before surgery and during follow-up

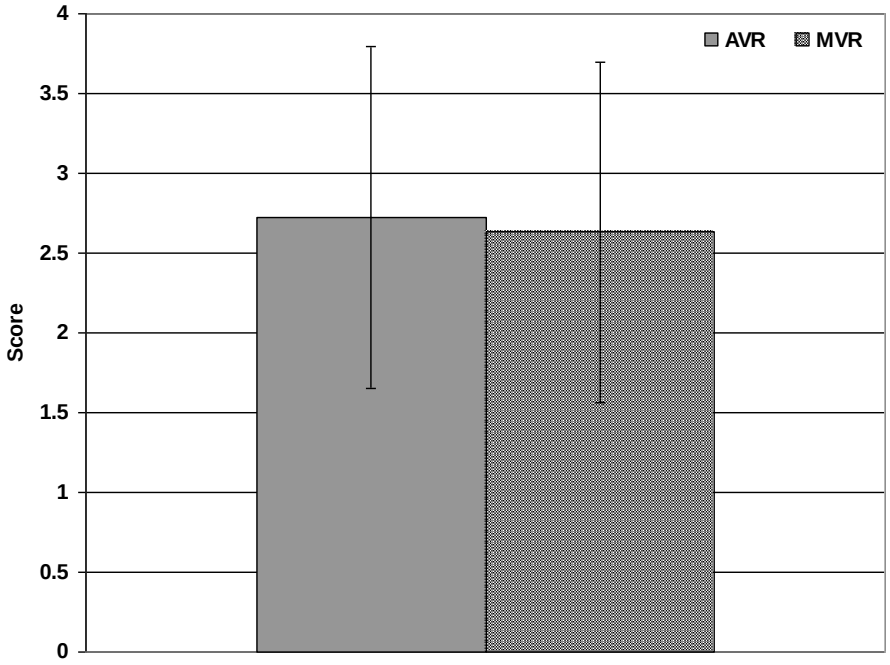

Fig. (2): Mean (±SD) satisfaction score of studied patients categorized according to valve replaced

Discussion

The current study reported favorable outcome of valve replacement using Cardiamed prosthetic valve manifested functionally as significant improvement of patients' distribution among NYHA classing system with significantly better mean total score compared to preoperative data. Moreover, implantation of Cardiamed valve significantly reduced the pressure gradient across the valve both in case of AVR and MVR. In line with these data; **Nemchenko & Eliseev** [14] evaluated the results of MedEng "Cardiamed" bicuspid mechanical mitral valve implantation in comparison to St. Jude, ATS and Carbomedics valves and found the peak gradient on the prosthesis was significantly lower with MedEng and the survival rate, freedom from thromboembolism and reoperation rates were 98%, 95.9% and 99% after 1-year follow-up.

The 30-day mortality rate was 2.6% and the late-mortality rate was 2.6% for a total mortality rate of 5.2% till the end of 20 months follow-up. In hand with these data, **Zheleznev et al.** [8] reported a hospital mortality rate of 4.2% after MVR using Cardiamed prosthetic valve.

Moreover, the reported mortality rates coincided with that reported with the implantation of other types of prosthetic valves; **Van Nooten et al.** [15] reported an in-hospital mortality rate of 4%. **Rodrigues et al.** [16] reported operative mortality for AVR and MVR of 7% and 7.5%, respectively with freedom from late mortality was 81.8% at 10 years for MVR and 83% for AVR, and freedom from valve-related death at 10 years for the MVR cohort and AVR was 85.6% and 88.7%, respectively. **Kaer et al.** [17] found that 4.9% of their series died of postoperative complications and concluded that valve replacement surgery is still an effective therapy for valvular diseases in Xinjiang area and enhancing preoperative care for elders and patients with poor cardiac function can decrease the perioperative complications and mortality rate so as to improve the surgical efficacies. **Taniguchi et al.** [18] reported early death within 30 days after ATS Open Pivot mechanical valves implantation of 2.5 % and a total 10-year survival rate after the operation of about 82.7%.

On contrary, the reported mortality rates were lower compared to **Ragnarsson et al.** [19] who reported a 30-day mortality rate of 9% after isolated MVR and attributed this high figure to the severity of the underlying heart disease.

Concerning valve-related complications; 3 cases (7.7%) had PVL which was mild and managed conservatively. The reported frequency of PVL was low compared to that reported by **Wąsowicz et al.** [20] who found a total rate for PVL of 12% and its presence was associated with postoperative infection. However, in line with the conservative management, **Wąsowicz et al.** [20] found that at the 1-year transthoracic echocardiographic follow-up detected only 2 of 27 patients had residual leak after MVR and none after AVR. Also, **Cho et al.** [21] documented that in patients who develop PVL after AVR, repeat surgery may be deferred, while in patients with PVL after MVR, more aggressive therapeutic approaches should be considered. **Kuwabara et al.** [22] explored the pathogenesis of PVL after valve replacement and attributed leak after AVR to laxation of sutured threads without frequent sites, while after MVR to cutting annulus tissue around the anterior commisurae after MVR.

As regards infective complications, 9 patients developed infections; 2 of them had valve-related endocarditis, but unfortunately, one patient showed deterioration and developed a stroke on the 13th PO day and died on the 18th PO day. Such event could not be attributed to faulty anticoagulant therapy nor to valve-related thrombosis, as this is the only event recorded throughout the follow-up period and considering this case to be unique in the series it represents a frequency of 1.3% /patient-year of follow-up which coincided with that previously reported by **Taniguchi et al.** [18] who found the incidence of valve-related complications with the ATS mechanical heart valve prostheses was 2.19 %/pt-yr; of these, the incidence of thromboembolic events and bleeding complications were 1.22 and 0.87 %/pt-yr, respectively.

The effectiveness and safety of the Cardiamed prosthetic valve and the follow-up free of valve-related thrombosis could be attributed to the inherent distinguishing features of this type of prosthesis; wherein the occluder is made as two leaflets that pivot from open position to closed position, the sewing cuff is made of special warp knitted polyester fabric, the valve housing is reinforced with a stiffening ring made of titanium alloy and the leaflets rotate around the central axis of the valve housing without restricting the rotating blood flow and eliminate the localization of all stasis zones in the bloodstream. Moreover, the valve generates the swirling of blood flow in

the heart chambers thus improving the washing of inner cardiac structures. The valve leaflets have a special aerodynamic shape for creating smoothly spreading blood flow, thus preventing blood flow turbulence and speeding valve closure and opening. The valve generates a controlled regurgitant blood flow for proper washing of its hinge mechanism. The valve has a barrier projecting above the sewing cuff that protects valve orifice from pannus ingrowth that covers sewing cuff [23, 24].

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