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Original Article

Nineteen Years of Single Institute Experiences with Sorin Bicarbon Prosthesis

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Purpose: We want to share our experience of Sorin Bicarbon prosthesis (SBP) after 19 years follow-up.
Methods: Retrospective study of 1377 patients who had replaced with SBP from May 1998 to December 2008 at Ho Chi Minh Heart Institute, Viet Nam.
Results: Male patients was 42%, mean age was 40.2 ± 11.8 years. Atrial fibrillation was 43.5%. The main cause of valvular disease was rheumatic fever (89.8%). Isolated mitral valve replacement (MVR): 54% (744), isolated aortic valve replacement (AVR): 18% (247), double valve replacement (DVR): 26% (359), and 27 AVR plus mitral repair. 30-day mortality for all was 1.5%. Mean time of follow-up was 153 ± 53.1 months with total follow-up time was 17563 patients-years. 2.5% lost of follow-up. Late death was 77 cases. Redo for all causes was 59 cases. 19 years survival was 88.8 ± 1.8%. 19 years freedom of redo was 76.4 ± 4.7%. Linearized rate of all valve thrombosis, embolism, severe bleeding, endocarditis, and pannus were 0.31%, 0.28%, 0.267%, 0.068%, and 0.165% patient-years, respectively.
Conclusions: SBP had shown very good results in long term and still have a reliable mechanical valve.

Keyword: sorin bicarbon prosthesis

Introduction

The Sorin Bicarbon prosthesis (SBP) (Sorin Biomedica, Saluggia, Italy and now with the new name is LivaNova Bicarbon) has been Food and Drug Administration (FDA) approved since 1990 and has shown very good early and medium-term results.[1,2] To date, there have two multicenter study, the first reporting a 15-year follow-up of 1704 patients from 12 European centers[3] and second, reporting a 5-year follow-up of 1351 patients from 15 centers in eight country.[2] In our institute, we started to use SBP from May 1998 to date and herein this article, we report a single-center experience of SBP with a follow-up of 19 years.

The SBP is a mechanical prosthesis with two leaflets made of pyrolytic carbon with a curved profile. About the structure, unique among mechanical heart valves, Bicarbon features curved leaflets specifically engineered to achieve an even flow distribution downstream. This leads to several major benefits to the patient such as minimum turbulence which avoids blood stasis and thus decreases the risk for thrombus formation and low pressure gradients for optimal hemodynamic performance. The leaflets, which open up to 80° from a 20º horizontal axis. The leaflet, the frame, and the sewing ring all are coated with a layer of Carbofilm™ which enhances hemo and biocompatibility.

Materials and Methods

Patient characteristics

After excluded all cases which were non-used SBP, a total of 1525 patients were reviewed. In all, 148 patients

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Table 1 Preoperative clinical characteristics and operative data

Characteristics	MVR *N*1 = 744	DVR *N*2 = 359	AVR *N*3 = 274
Sex: female	512 (69%)	197 (55%)	90 (32.8%)
Male	232 (31%)	162 (45%)	184 (67.2%)
Mean age (y ± SD)	41.3 ± 10.7 (5–69)	40.2 ± 9.9 (15–68)	37.1 ± 15.9 (7–77)
CTR	0.59 ± 0.07	0.61 ± 0.08	0.58 ± 0.07
Rhythm			
SR	365 (49%)	155 (43%)	258 (94.2%)
AF	371 (51%)	204 (57%)	16 (5.8%)
NYHA			
I	7 (0.9%)	1 (0.3%)	3 (1.1%)
II	627 (84.3%)	303 (84.4%)	218 (79.6%)
III	91 (12.2%)	52 (14.5%)	48 (17.5%)
IV	19 (2.6%)	3 (0.8%)	5 (1.8%)
LV EF	65.4 ± 7.4%	64.4 ± 7.7%	63.7 ± 10%
Systolic PAP	60.4 ± 20 mmHg	56.8 + 18 mmHg	38 ± 12.3 mmHg
Previous cardiac surgery			
Valve repair	76	2	12
Valve replace	7	5	6
Valve pathology			
Stenosis	320	na	92
Regurgitation	105	na	102
Mixed	219	na	80
Cause			
Rheumatic	713 (95.8%)	352 (98.1%)	172 (62.8%)
Endocarditis	19 (2.6%)	5 (1.4%)	21 (7.7%)
Degenerative	2 (0.3%)	1 (0.3%)	8 (2.9%)
Congenital	8 (1.1%)	1 (0.3%)	70 (25.5%)
Others	2 (0.3%)	0	3 (1.1%)
Concomitant surgery			
ASD, VSD closure	13	0	37
Thrombus ablation	86	23	0
Mitral repair	0	0	27
Tricuspid repair	243 (32.6%)	86 (24%)	8 (2.9%)
Coronary bypass	9	5	7
Others	23	17	16
Hospital death	17 (2.3%)	1 (0.3%)	2 (0.7%)

AF: atrial fibrillation; ASD: atrial septal defect; CTR: cardiothoracic ratio; LV EF: left ventricular ejection fraction; na: non-applicable; PAP: pulmonary artery pressure; SR: sinus rhythm; VSD: ventricular septal defect; NYHA: New York Heart Association; MVR: mitral valve replacement; AVR: aortic valve replacement; DVR: double valve replacement

were follow-up at other centers. The remaining 1377 patients are in our study. There were 578 men (42%) and 799 women (58%) with the mean age of 40.2 ± 11.8 years (range: 5–77 years). Almost the cause of valve pathology was rheumatic disease (89.8%). Preoperatively, 778 patients (56.5%) were in sinus rhythm and 599 patients (43.5%) were in chronic atrial fibrillation. 84% patients were in New York Heart Association (NYHA) functional class II and 16% patients were in NYHA functional class III and IV. Mean cardiothoracic ratio, left ventricular end diastolic diameter, and left ventricular ejection fraction were 0.6 ± 0.07, 51.5 ± 10.4 mm, and 64.8% ± 8%, respectively. In all, 113 (8.2%) patients underwent reoperation. Mitral valve replacement (MVR) was performed in 744 patients (54%), AVR in 274 (19.9%), and double valve replacement (DVR) in 359 (26.1%). Data details of subgroup are shown in **Table 1**.

Follow-up and data acquisition

After discharge, all patients were entered in our follow-up protocol, which includes serial clinical examen at time of 1-, 3-, 6-, and 12-month postoperation in 1st year; 6th and 12th months in 2nd year and then once examen per year. Every regular examen in our institute included clinical examen, X ray, echocardiography, and international normalized ratio (INR) test. All information

of clinical status, valve-related and non-related complications, and valve performance were recorded which were assessed according to well-established guidelines.[4] Those unable to come back to our institute or follow-up in another hospital were excluded to study. Patients not return to re-examen and cannot contact by phone or mail were defined as lost of follow-up. In all, 32 patients (2.5%) had lost to follow-up. Data were retrieved from our local database and medical record. The follow-up of the current series was closed in Mars 2018. Our clinical study has approved by ethical committee of our institute. Cumulative duration of follow-up is 17 653 patient-years in the entire group; 9420.5 patient-year for MVR, 3362.7 patient-years for AVR, and 4779.6 patient-years for DVR. For all patients, mean follow-up is 153.1 ± 53 months ranging from 86 to 236 months.

Statistics

Continuous variables are reported as the mean ± standard deviation and the categorical variables are represented as numbers (percentages). The actuarial survival and postoperative complication-free rate are evaluated by the Kaplan–Meier method. Valve-related complications included thrombosis, thromboembolism, anticoagulant-related bleeding, endocarditis, and re-operation are presented as linearized rates.

Surgical technique

All operations were performed through a fully median sternotomy. Cardiopulmonary bypass was established with the ascending aorta and bicaval venous cannulation with moderate systemic hypothermia (28–32°C). To protect the heart, cardioplegia was performed by antegrade cold crystalloid cardioplegia into the aortic root or coronary ostia every 20 minute and topical cooling throughout the procedure; retrograde cardioplegia was only occasionally used. We used cardioplegia liquid homemade (based on St Thomas cardioplegia formula) in period 1998–2007 and Sterile Cardioplegia Concentrate (Hameln Pharmaceutical-Germany) in 2008–2017. For AVR cases, the left ventricle was vented through the right upper pulmonary vein or trans-right ventricle with 16F needle. Prostheses were implanted using 2/0 nonabsorbable sutures reinforced by Teflon felts (Ethicon, Johnson and Johnson) placed in supra-annular everting position. The posterior mitral leaflet with its chordal attachments was partially conserved whenever technical feasible for MVR. Prostheses were mainly oriented in the anti-anatomic position for MVR and in position with one hinge facing the interventricular septum for AVR. In cases of important tricuspid regurgitation associated, tricuspid annuloplasty with Carpentier-Edwards rigid ring or autologous pericardial strip treated with glutaraldehyde. All thromboses in left atrial or left appendage are removed carefully and closed them with double layer continuous suture. Distal coronary anastomoses were always performed before valve replacement. Other associated procedures are as follows: closing atrial septal defect and ventricular septal defect: 50, thrombosis ablation: 109, mitral valve repair: 27, tricuspid repair: 337 (24.5%), and coronary artery bypass: 21.

All patients were given intravenous heparin starting from the first postoperative day after bleeding has stopped. Acenocoumarol (Sintrom™) or Warfarin (Coumadin™) therapy was started after extubation, usually on postoperative day 1. When a target INR of 2.5 for AVR (range: 2–3) and 3 for MVR or DVR (range: 2.5–3.5) was reached, heparin was suspended. No patient was routinely given antiplatelet drugs excepted patients had an episode of thrombosis.

The most common size of SBP in aortique position is 21 mm: 303 and then 23 mm: 201. In mitral position, the most common size is 27 mm: 471 and then 29 mm: 278 patients.

Results

Operative mortality and survival

In all, 20 patients died in 30-day postoperation (1.5%), mortality mainly was in MVR group (17 patients), only one patient in DVR and two patients in AVR. Causes of hospital mortality were as follows: low cardiac output in 10 patients, multi-organ failure in 3, sepsis in 3, myocardial infarction in 1, sudden death in 1, cerebral vascular accident in 1, and left ventricular rupture in 1 patient.

Late death was 77 patients, after MVR: 36, after DVR: 14 and after AVR: 27. In which, 43 cases were considered as valve-related, with a linearized incidence of 0.43%/patient-year; these deaths were caused by cerebral hemorrhage in 16, chronic heart failure in 15 patients, sudden death in 12, cancer in 8, unknown in 7, renal failure in 4, endocarditis in 2, myocardial infarction in 1, and other causes in 12.

Actuarial survival rates (including surgical mortality) at 10 years were 94.6% ± 0.6% overall, 92.2% ± 1.7% for AVR, 94.3% ± 0.9% for MVR, and 95.8% ± 1.1% for DVR, and those at 19 years were 88.8% ± 1.8%,

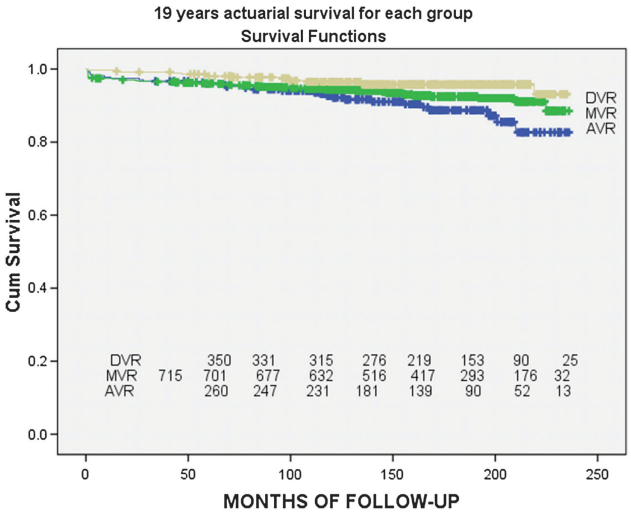

Fig. 1 19 years actuarial survival for each group. DVR: double valve replacement; MVR: mitral valve replacement; AVR: aortic valve replacement

80.6% ± 4.5%, 90.9% ± 1.5%, and 93.1± 2.8%, respectively (**Fig. 1**). Valve-related death occurred in 21 patients in the AVR group, 26 in the MVR group, and 12 in the DVR group. Rates of freedom from valve-related death at 10 years were 96.7% ± 0.5% overall, 94.3 ± 1.5% for AVR, 97.2 ± 0.6% for MVR and 97.1 ± 0.9% for DVR, and those at 19 years 93.5 ± 1%, 86.1 ± 3.6%, 94.6 ± 1.3%, 96.3 ± 1.1%, respectively (p = 0.005). Of the 1280 current survivors, 1190 are in NYHA class I, 76 are in class II, and 14 are in class III.

Thromboembolism

In all, 53 episodes of thromboembolism have occurred in 50 patients (three patients had two times thromboembolism) which included the following: transient ischemic attack in 36 cases, moderate to severe ischemic stroke in 14 cases, in which 4 deaths and 10 alive and all cases were recoverable nearly completing except 4 had permanent sequelae. Rate of freedom from thromboembolism at 10 years were 99% ± 0.3% overall, 99.1% ± 0.6% for AVR, 99% ± 0.4% for MVR and 99.4% ± 0.5% for DVR, and those at 19 years were 82.9% ± 4.8%, 80% ± 6.3%, 78.8% ±8.9% and 90.2% ± 3.2%, respectively (p= 0.292).

Valve thrombosis

In 93.7% of cases, we used Acenocoumarol (Sintrom™) oral twice a day and 6.3% patients used Warfarin (Coumadin™) once a day. Although we try to keep INR from 2.5 to 3.5 for MVR and 2 to 3 for AVR, valve thrombosis had occurred in 55 patients (59 episodes, two patients had occurred three times). They included the following: 38 patients in MVR (5.1%), 13 in DVR (3.6%), and 4 in AVR (1.5%). We performed fibrinolysis for 38 patients and completely success in 24 cases. In total, 31 cases have to reoperate to change a new prosthesis. We used mostly Streptokinase (32 cases) and rTPA (Actilyse®) for fibrinolysis. With Streptokinase, loading dose was 250,000 UI intravenous in 30 minutes and then maintain a dose of 1.5M UI intravenous in 10 hours. If failed, the 2nd maintain dose was performed. With rTPA, loading dose was 10 mg and then 90 mg intravenous in 3 hours. Transoesophageal echo (TEE) was performed before and after fibrinolysis to evaluate the results. Majority of valve thrombosis were female patients: 80%. Causes of valve thrombosis were as follows: irregular taking drugs in 27 cases (50%); 8 patients have stopped using anticoagulant completely; during pregnancy: 5 (9%); temporary stopped due to extra-cardiac intervention: 10 and other causes: 5. The overall incidence of valve thrombosis was 0.31%/patient-year.

Hemorrhages

Anticoagulant-related hemorrhages were observed in 239 patients. We divided into two levels: (1) mild to moderate when patients have bleeding mucosal skin such as petechia, gingival bleeding: 192 patients; (2) severe hemorrhage when patients have to re-admitted for gastro-intestinal tract or cerebral hemorrhage: 47 patients. In all, 16 patients died after cerebral hemorrhage. Linearized incidence of severe hemorrhage is 0.267% patient-year. Rates of freedom from hemorrhagic complications at 10 years were 98.5% ± 0.3% overall, 98.6% ± 0.8% for AVR, 98.2% ± 0.5% for MVR and 98.1% ± 0.8% for DVR and those at 19 years were 91.6% ± 1.7%, 91.8% ± 4.5%, 89% ± 3%, and 95.6% ± 1.6%, respectively (p = 0.461).

Perivalvular leak

A periprosthetic leak was observed in one patient 3 years after MVR (non-related endocarditis) and three patients after AVR (all cause by late endocarditis) giving an incidence of 0.023% /patient-year; one patient died at reoperation in low cardiac state.

Endocarditis

In all, 10 cases of endocarditis were recorded with a linearized incidence of 0.056% /patient-year. In which, four cases were early endocarditis in the first year after operation (two cases were recurrent endocarditis in

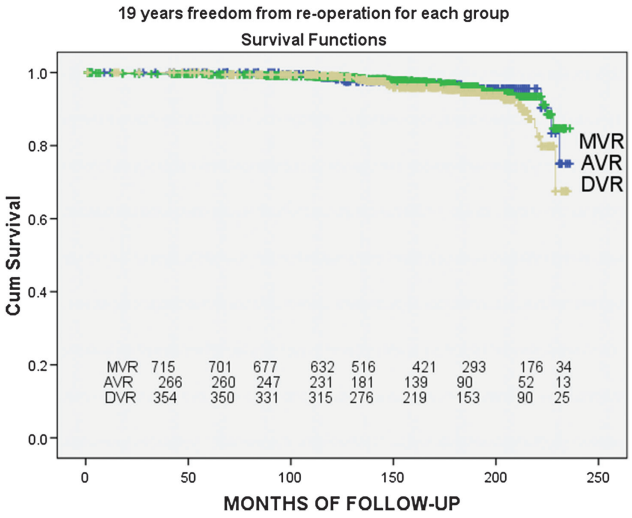

Fig. 2 19 years freedom from reoperation for each group. MVR: mitral valve replacement; AVR: aortic valve replacement; DVR: double valve replacement

aortic position with the same agent is *Staphyloccocus aureus*, both required reoperation sub-urgent). Six cases left, endocarditis occurred 3 to 5 years after surgery and 02 cases need to redo. 02 patients died of sepsis before reoperation. Freedom from prosthetic valve endocarditis at 19 years were 95.8% ± 3.1% overall, 86.8% ± 9.3% for AVR, 99.6% ± 0.4% for MVR, and 99.3% ± 0.5% for DVR.

Reoperation

During 19 years follow-up, 59 patients required reoperation (shortest, 1 month and longest, 186 months post-primary operation). Causes included for three groups: valve thrombosis: 31, pannus ingrowth: 16, endocarditis: 6, para-valvular leak: 3, mitral insufficiency recurrent: 2 and remove new thrombus in left atrium 1. Overall incidence of reoperation is 0.31%/patient-year. Rates of freedom from reoperation at 5 years were 99.6% ± 0.2% overall, 100% for AVR, 99.4% ± 0.3% for MVR, 99.7% ± 0.3% for DVR, and those at 10 years were 98.8% ± 0.3%, 98.1% ± 0.9%, 98.6% ± 0.5% and 98.7% ± 0.6%, respectively. At 15 and 19 years, rates of freedom from reoperation were 96.2% ± 0.7% and 82.7% ± 3.4% , 95.6% ±1.7% and 83.4% ± 8.3%, 96.5% ± 0.9% and 84.7% ± 5.2%, 94.6% ±1.5% and 67.5% ± 9.1%, respectively (p = 0.241) and shown in **Fig. 2**.

Structural failure: no prosthesis structural failure has been observed in our series.

Non-structural dysfunction: two cases had mild para-valvular leak (AVR) without hemolysis and no need to redo. Another three cases (two in mitral and one in aortic position) need to reoperation for refixation or replacement for a new one. No case hemolysis has been observed. 29 cases pannus formation all in aortic position, among that 16 cases had to reoperate for resection pannus and changement a new prosthesis.

Major adverse valve-related event

Overall, major adverse valve-related event occurred in 156 patients with an incidence of 0.88%/patient-year in the entire series (AVR 26 events, MVR 79 events, and DVR 51 events). Causes were presented in **Table 2**. Actuarial freedom from all valve-related complications at 10 years were 96.8% ± 0.5% overall, 96.6% ± 1.2% for AVR, 96.51% ± 0.7% for MVR and 96.7% ± 1% for DVR. And those at 19 years were 61.5% ± 4.1% overall, 65.3% ± 8.4% for AVR, 67.1% ± 5.2% for MVR and 65.1% ± 5.8% for DVR (p = 0.596).

Discussion

The Sorin Bicarbon bileaflet was received approval from the FDA in 1990. In our institute, we started to use SBP from May 1998 and after that we also used another kind of bileaflet mechanical prosthesis such as Saint Jude Medical, Medtronic ATS, OnX, CarboMedics. Here, we retrospect a case series of valve replacement to evaluate the long-term results. Until now, this study is the largest series of SBP replacement in Viet Nam and ASEAN. Two meta-analysis of Borman and Azanoush in Europe showed a low rate of valve-related complications and no case had structural failure in long-term follow-up with SBP. The authors concluded that the use of SBP continues to perform satisfactorily 15 years post-implantation and can be considered a valid alternative to other mechanical valve substitutes, particularly in view of its excellent long-term durability.[2,3] A study of Celiento et al. with 17-year follow-up also showed excellent results with actuarial freedom from valve-related deaths, embolism, and bleeding are very high.[5] Our study also showed the same results after 19 years follow-up except some complications. In our series, the rate of thromboembolism and bleeding related with anti-vitamin K drug were lower but the rate of valve thrombosis was higher significantly (**Table 3**). It could be closely related with using anti-vitamin K drug and routine INR examen. In our institute, we used mostly Acenocoumarol (93.7%) instead of Warfarin to maintain INR in therapy zone (according to guidelines of European Society

Table 2 Major adverse events in each groups

Major events	AVR	MVR	DVR
Total follow-up (months)	147.3 ± 53.2 (3362.7 pat-year)	151.9 ± 54.5 (9420.5 pat-year)	159.8 ± 49.2 (4779.6 pat-year)
Late death	27 (9.9%)	36 (4.8%)	14 (3.9%)
Thromboembolism	13 (4.7%)	24 (3.2%)	13 (3.6%)
Valve thrombosis	04 (1.5%) Fibrinolysis = 3	38 (5.1%) Fibrinolysis = 26	13 (3.6%) Fibrinolysis = 9
Endocarditis	7 (2.6%)	2 (0.2%)	03 (0.9%)
Para-valvular leak	02	01	03 (0.9%)
Pannus formation	06 (2.2%)	0	23 (6.4%)
Bleeding			
Mild or moderate	31 (11.3%)	104 (14%)	57 (15.9%)
Severe	7 (2.6%)	29 (4%)	11 (3.1%)
Reoperation	10 (3.6%)	26 (3.5%)	23 (6.4%)

AVR: aortic valve replacement; DVR: double valve replacement; MVR: mitral valve replacement

Table 3 Compare valve-related events in long term (%/pt-y) between SBP and another prosthesis

Valve type (authors, year)	Thrombosis	Thromboemboli	Bleeding	Endocarditis	Non-structural failure	Reoperation
Bicarbon						
Azarnoush, 2010	0.10	0.81	1.46	0.22	0.51	0.4
Spiliopoulos[15], 2009	0.04	1.33	1.21	0.16	0.7	0.69
Borman, 2002	0.27	1.14	0.8	0.37	0.31	0.59
Celiento, 2014	0.09	0.34	0.2	0.05	na	0.11
Misawa, 2015	na	0.5	0.5	0.2	na	0.4
Our study, 2018	0.44	0.35	0.41	0.08	0.02	0.31
CarboMedic						
Tominaga[16], 2005	0.11	1.47	0.65	0.19	0.46	0.73
Kang[17], 2005	0.25	0.75	0.8	0.3	0.074	0.23
Bouchard[18], 2014	0.13	0.59	0.57	0.22	na	0.72
SJM						
Ikonomidis[19], 2003	0.1	1.3	2.7	0.22	na	0.22
Remadi[20], 1998	0.21	0.75	0.91	0.14	0.48	0.42
Medtronic ATS						
Sezai[12], 2010	0	0.44	0.19	0	0.12	0.06
Baykut[21], 2006	0.04	1.1	0.5	0.1	0.6	0.24

na: non-applicable

Cardiology): 2–3 for aortic valve and 2.5–3.5 for mitral position. When analyzed in 55 patients who suffered valve thrombosed in this series, a half of patients have fail to comply anticoagulant treatment and INR follow-up. Almost these patients have lived in remote province. Like conclusion of Durrleman, inadequate level of anti-coagulation is the most important factor involved in the pathogenesis of prosthetic valve thrombosis.[6] In recent years, we begin to use self-control CoaguChek XS system (Roche Diagnostics, France) for patients who could not follow-up frequently and this machine has improved the INR follow-up. In general, when compared with another prosthesis, SBP have the same events in long-term follow-up.

The most common size of prosthesis using in this study were 27 mm in mitral position and 21 mm in aortic position. Comparison with Azanoush, Borman, Celiento, de Carlo, Misawa, the sizes corresponding with mitral and aortic position were 29 and 23 mm.[2,3,5,7,8] It is logical because Vietnamese patient's BSA is smaller than European patients.

The phenomena of pannus ingrowth or over growth: in total of 1186 patients who have replaced with Metronic-Hall prosthesis, Ellensen reported 27 cases (2.3%) existed pannus ingrowth after valve replacement 11.1 year and 7 patients among that had died before redo.[9] Sakamoto reported the rate of pannus of Bijork-Shiley prosthesis is 2.4% and St Jude Medical prosthesis is only 0.73%.

The authors suggest that activation of invasive tissue formation in a mono-disk valve is due to turbulence blood flow through the small opening.[10] In our study, this rate is 4.6% (29 cases) higher than other study. In our series, 25/66 patients with size 17S to 19S have emerged tissue overgrowth beneath the aortic valve after a median time of 7.5 year. Almost all of them belong to the DVR group, whereas size 21 or larger are dominated in AVR group. And no patient was changed with size 17S in AVR group. With size 21 mm, there had only four cases that have pannus ingrowth. In fact, there are very few clinical symptoms in almost patients but we doubt that when there are signs such as (1) patients was replaced valve prosthesis at least 7 years; (2) echocardiography showed anormal high trans-valvular gradient and TEE recorded tissue overgrowth image beneath the valve; and (3) fluoroscopy showed anormal movement of leaflet (eliminated leaflet trapped due to thrombosis). Pannus ingrowth phenomenon may lead to secondary patient-prosthesis mismatch (PPM) syndrome. A meta-analysis of Head et al. (in 23,186 patients) showed that PPM increased the rate of valve-related death in long term.[11] Sezai recorded in echocardiography 83.3% patients bearing 19 mm valve have had moderate to severe PPM.[12]

Another study of Kaminishi (3609 patients with AVR) showed the rate of PPM is very high: 8.5% and early mortality rate in PPM group is 3.9% versus 1.8% only in no PPM group.[13] Therefore, to prevent this phenomenon, it should be consider to use supra-annular prosthesis with smallest size of 21 mm in adult patient. In case of small annular aortic, we propose to enlarge annular aortic with Manougian or Carpentier's technique. In three cases of redo, we were able to increase two size of aortic prosthesis with Konno-Rastan technique. At last, we do not recorded any case of hemolysis after valve replacement with SBP as Josa reported.[14]

Conclusion

With very good long-term results, SBP represents an excellent choice for both aortic and MVR. In adult patients, minimum size of aortic prosthesis should be 21 mm for better long-term results and reduce the rate of PPM phenomenon.

Disclosure Statement

I do not have any relevant financial relationship to disclose.

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