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Early postoperative hemodynamics and clinical outcomes of patients receiving freedom solo aortic calve replacement; the Asian Experience

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Summary

Aim: Background and aim of the study: Freedom SOLO (FS) valve (Sorin Group, Saluggia, Italy) is a stentless aortic valve bioprosthesis that use a single running suture line implanted in supra-annular position. Current study aims to assess the early postoperative hemodynamics and clinical outcomes of patients receiving FS aortic valve replacement (AVR).

Methodology: 4 patients (2 male; 2 female; mean age 49.25 ± 23.78 years; range: from 25 to 73) who underwent AVR with FS valve in a single center were enrolled in the study. 2 patients underwent AVR for aortic stenosis and 2 patients for aortic regurgitation. Clinical and biological outcomes were recorded. Echocardiographic parameters were compared between preoperative and 5 months postoperative observation.

Results: There was no early mortality reported. Late death was reported in one patient which was non valve related. There were 2 patients who developed early postoperative complication but it was not attributed to the valve itself. The mean transvalvular pressure gradient was 26.50 ± 11.90 mmHg preoperatively and 15.25 ± 10.11 mmHg postoperatively. The mean aortic valve area (AVA) for patients having stenosis improved from 0.74 ± 0.23 cm2 preoperatively to 1.50 ± 0.57 cm2 postoperatively. Preoperatively, the mean left ventricular ejection fraction (LVEF) was 65.75 ± 6.29 % and postoperatively 61.25+_11.84 %. The mean cross-clamp time (CCT) for isolated valve replacement was 80.5 ± 21.92 minutes and 147.00 ± 26.87 minutes. The mean lowest postoperative platelet count recorded was 24.50 ± 6.19 (x109/L). The mean platelet count at discharge was 128.75 ±10.11 (x109/L).

Conclusion: The result demonstrated good short-term clinical and hemodynamic outcomes in patients underwent FS aortic valve replacement. However, the study also showed the occurrence of severe thrombocytopenia after FS valve implantation.

Keywords: freedom solo valve, thrombocytopenia, aortic valve replacement

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Introduction

Aortic valve replacement (AVR) with aortic valve prosthesis is a common cardiac surgical procedure in order to substitute the pathological native aortic valve. It has been widely implemented since it gives a good long term outcomes and low risk of perioperative mortality and morbidity.[1, 2] There are two types of valve that are commonly used in aortic valve replacement, which are mechanical valve and bio prosthetic valve. [3, 4] Mechanical valve is well known for its long term durability but the disadvantage of its use includes risk of thrombogenic event necessitating lifelong anticoagulant. This imposes the user on risk of hemorrhage. In contrast, the use of bio prosthetic valve is less associated with thrombotic event and thus the use of long term anticoagulant therapy is not needed. Hence, bio prosthetic valve is increasingly being used.

Initially, the stented bio prosthesis has been applied. However the durability of this valve has been questioned since many studies revealed that it has the propensity to develop structural valve deterioration.[5] Since both types of valves have the disadvantages that limit the use of it, the stentless valve had been introduced. Stentless bio prosthesis is becoming a valid choice due to its potential hemodynamic improvement compared to stented bio prostheses.[6] Several stentless valves are available at the present time, opening a bigger spectrum of choice to meet the patients' and surgeons' requirement.

One of these is the Freedom SOLO (FS) valve which is a new generation stentless bio prosthesis that has been released by the Sorin Company (Saluggia, Italy) in June 2004. FS is a stentless biological aortic valve which is implanted supra-annularly with a single suture line. It is formed from two sheets of bovine pericardium which is sewed together.[7] Since it is a biological tissue, this valve needs to be fixed first with glutaraldehyde.

The presence of remain free unbound aldehyde group may give rise to the inflammatory response after implantation.[8] Thus, in order to neutralize and eliminate any free aldehyde groups, the prosthesis will be detoxified using homocystic acid. Though it undergoes detoxification treatment, the stability and the mechanical properties provided by the glutaraldehyde cross-linking is not compromised thus improving the biocompatibility and potential durability of the prosthesis. [8] This stentless bio prosthesis also undergo anti calcification process in order to avoid the complication of postoperative structural deterioration that has been associated with stented bio prosthesis.[9] Later, the valve is stored in an antibiotic solution and ready to use. This valve does not require any rinsing before implantation. [10] It is very convenient and well known for its short cross clamping time attributed to its single suture line. [11] Due to its fast implantation, this will significantly reduce post-operative adverse events in both low and high risk patients. From the current observation, the use of FS valve also showed an excellent outcome in both short and medium term postoperative observation.[11, 12]

Although the implantation of the valve gives positive hemodynamic outcome in most of the researches, the advantages are still not established since the use of the valve is still new.

Therefore, this present study aims to assess the early postoperative hemodynamics and clinical outcomes of patients receiving FS aortic valve replacement (AVR). It was a retrospective cohort study where 4 patients, operated from July 2010- April 2011 with implantation of FS aortic pericardial valves in our centre UMMC (University Malaya Medical Centre) were assessed within 5 months postoperatively. Clinical outcome, surgical outcome, platelet levels, echocardiography and follow-up data recorded prospectively.

Malaysia is the first Southeast Asia country using the FS aortic valve. Previously, our centre use mechanical and stented bio prosthesis. Due to the advantages of this bio prosthesis, our center started to adopt it in July 2010. Although the valve has been use widely, there was a limitation. Many research found that the use of this valve was associated with postoperative thrombocytopenia.[13, 14, 15, 16] However, research conducted by Beholz et al. found none of the study reported severe thrombocytopenia as an adverse event.[17] Hence, in spite of increase in the usage of FS valve, there is still controversy regarding its complication.

Material and Method

- **Patient**

Between July 2010 and April 2011, a total of 4 FS valves were implanted in 4 patients at the cardiotho-

racic surgery departments in UMMC. The patients' age ranges from 25 to 73 years old. Patient demographic, clinical and surgical characteristics including age, sex, body surface, logistic Euro SCORE (European System for Cardiac Operative Risk Evaluation), risk factors, concomitant procedures, preoperative platelet count, valve lesion, valve size, and cross clamping time (CCT) were recorded and tabulated in Table 1.

The inclusion criteria for FS valve replacement were stenosis and regurgitation, 2 patients each. The exclusion criteria for FS valve replacement were extensive calcification of the aortic root as it may cause difficulty in suturing and congenital bicuspid aortic valve. It is contraindicated due to increased risk of misalignment of the prosthesis at the implant site.

Preoperatively, all patients were in NYHA functional class II and in sinus rhythm. There were no emergency cases. The mean left ventricular ejection fractions (LVEF) which were taken one day before operations was 65.75 ± 6.29%. Patients' preoperative mean transvalvular pressure gradient was 26.50 ± 11.90 mmHg and mean aortic valve area (AVA) for patients having stenotic valve was 0.74 ± 0.23 cm2. Preoperatively, the platelet count for all the patients were within normal range. The mean preoperative platelet count was 217.50 ± 49.142 (x109/L). Since the patients' identity were not exposed in the study, individual patient consent was not required. All the outcome parameters were tabulated in Table 2 and Table 3.

Operative technique

All the implantations were performed by a single senior consultant cardiac surgeon. The FS valve was implanted with a supraannular technique, using in all cases one continuous suture line in the sinuses of Valsalva. Associated procedures were performed in 2 patients. One patient had concomitant coronary artery bypass graft (CABG) procedure while the other patient had ventricular septal defect (VSD) closure, mitral valve ring annuloplasty and closure of anterior mitral valve leaflet perforation. All 4 patients had used different prosthesis valve size including 19mm, 21mm, 23mm and 27mm. The mean implanted valve size was 22.5000 ± 3.41565 mm.

Table 1. Demographic, clinical and surgical characteristic of the study patients

Parameter	Value
Gender (n)	
Male	**2**
Female	**2**
Mean age (years)	**49.25 ± 23.78**
Mean body surface area (m2)	**1.60 ± 0.22**
Valve lesion (n)	
Stenosis	**2**
Regurgitation	**2**
Mean logistic Euroscore (%)	**2.10 ± 0.81**
Risk factor and other preoperative condition (1) (n)	
Hypertension	**1**
Hypercholesterolemia	**1**
Stroke	**1**
Infective endocarditis	**1**
Ventricular septal defect	**1**
Type 2 Diabetes Mellitus	**1**
Benign prostatic hyperplasia	**1**
Chronic rheumatic heart disease	**1**
Labelled valve size (n)	
19 mm	**1**
21 mm	**1**
23 mm	**1**
27 mm	**1**
Concomitant procedure (2) (n)	**2**
Mean preoperative platelet count (x 109/L)	**217.50 ± 49.14**
Average cross clamping time (min)	
Isolated procedure	**80.50 ± 21.92**
Concomitant procedure	**147.00 ± 26.87**

- *The patients can have more than one risk factor*
- *Concomitant procedures are coronary artery bypass grafting, ventricular septal defect closure, mitral valve ring anuloplasty, closure of anterior mitral valve leaflet perforation*

Table 2. Haemodynamic results

Parameter	Value	
	Preoperative	Postoperative
Mean aortic valve area (AVA)(1) (cm2)	**0.74 ± 0.23**	**1.50 ± 0.57**
Mean transvalvular pressure gradient (mmHg)	**26.50 ± 11.90**	**15.25 ± 10.11**
Mean left ventricular ejection fraction (LVEF) (%)	**65.75 ± 6.30**	**61.25 ± 11.84**

- ***Only for patients having stenotic valve***

Clinical assessment and follow up

For each patient, medical history including physical examination, electrocardiogram, and medication assessment were obtained before the operation. Postoperatively, the patients were monitored to assess any complication. Once the patient had been discharged, follow up examination were carried out at the outpatient clinic. Data including clinical and echocardiography finding were collected within the first 5 months postoperatively. Analyzed endpoints were postoperative hemodynamic performance, clinical outcome and the occurrence of thrombocytopenia.

Preoperative, postoperative echocardiography

The hemodynamic performance of the FS valve was assessed using quantitative transthoracic echocardiography. Echocardiography examinations were performed preoperatively and within 5 months after AVR. The echo-Doppler data of each patient were analyzed by an experienced echocardiographer (> 10years experience). All data were stored digitally.

Surgical procedure

After the institution of general anesthesia, a median sternotomy was performed. Mild hypothermic environment (32°C) and cardiopulmonary bypass (CPB) instituted. A transverse aortotomy was performed 0.5 cm above the sinotubular junction after aortic cross-clamping. Then, intermittent cold blood cardioplegia administered via the coronary ostia. Inspection of the valve, leaflet resection and careful annular decalcification followed. Following that, sizing was performed according to the annular diameter. FS valve was implanted with a continuous supraannular suture line technique using three 4-0 prolene monofilament running sutures starting

Table 3. Postoperative clinical and biological outcome of patients

Parameter	Value
Clinical event (n)	
Early complication	
Haemorrhage	**1**
Ischaemia	**1**
Low cardiac output syndrome	**1**
Late complication	**0**
Death	**1**
Mean postoperative hospital stay (days)	**3.00 ± 0.82**
Mean lowest postoperative platelet count (x 109/L)	**24.50 ± 6.19**
Mean platelet count at discharge (x 109/L)	**128.75 ± 63.20**

at the deepest point of each sinus valsalva and continued to the top of the commisures. The three sutures were then tied outside of the aortic wall without reinforcement. The implantation technique was consistent with the recommendations of the valve manufacturer. After deairing of the left ventricle and aorta, cross-clamp was released and the patient was weaned from CPB.

Statistical analysis

Data was stored and analysed using the SPSS statistical software (SPSS 17.0, SPSS; Chicago, IL). Descriptive statistics including frequency and mean were used for data description. Continuous data are expressed as means ± standard deviation. Categorical data are expressed as percentages.

Result

Changes in the hemodynamic parameters are listed in Table 2. Postoperative transvalvular pressure gradient was 15.25 ± 10.11 mmHg. Postoperative LVEF was 61.25±11.84 %. Postoperative AVA for patients having stenosis was 1.50 ± 0.57 cm2. The mean CCT for isolated valve replacements was 80.5 ± 21.92 minutes and 147.00 ± 26.87 minutes with associated procedures. The mean for the lowest postoperative platelet count recorded was 24.50 ± 6.19 (x109/L). The mean platelet count at discharge was 128.75 ±10.11 (x109/L). The mean for the duration of postoperative hospital stay was 3.00 ± 0.82 days.

Early complication which was considered within 30 days postoperative occurred in 2 patients. One patient had haemorrhage from the sternal puncture site a day after the valve replacement. The other one patient had left hand ischaemia and low cardiac output syndrome 20 days post operation. There was no late complication associated with the valve replacement noted up to the first 5 months postoperative. One case of late death reported 4 months postoperatively which was described as non valve related. Postoperative clinical and biological outcome of patients are listed in table 3. Further follow up done to assess the late complications. During follow-up, there was no incidence of structural valve degeneration or paravalvular leaks which assessed by clinical examination and echocardiographic evaluation.

Discussion

There was an occurrence of transient severe thrombocytopenia (30x 109/L) in patients who received the Sorin FS bio prosthesis within the first few days after implantation. The mean lowest postoperative platelet count was recorded as 24.50 ± 6.19 (x109/L). 3 (75%) out of 4 patients had severe postoperative thrombocytopenia. Similarly, there were some researches done previously that suggest postoperative thrombocytopenia.[7, 13, 15] Research done by Piccardo A and associates in Amiens-Picardie University Hospital, Amiens, France reported the risk of thrombocytopenia was high after FS valve implantation.

The result showed severe thrombocytopenia (<30 x 109/L) occurred in 8 (22%) out of 36 patients with a FS bio prosthesis.[13] This finding corroborated to the previous study done by Kolseth SM and associates in Norway demonstrated 28 (76%) out of 37 patients had a minimum postoperative thrombocyte level less than 100x109/L.[7] Another study done by Tarzia V and associates in University of Padova, Italy showed the same result. Their study between March 2009 and February 2011 revealed 21 (70%) out of 30 consecutive patients undergoing Sorin FS aortic valve implantation had a postoperative thrombocytopenia (<100x109/L) within the first five postoperative days. In addition, the platelet functional test (ROTEM® and MULTIPLATE® tests) which was held in their study demonstrated the transient thrombocytopenia was not due to qualitative changes of the platelet.[15]

The reason behind it is still unknown. However there was a study done by Yerebakana C and associates postulated the possible cause maybe originating from the FS valve. FS valve is said to give transitory direct toxic effect on platelets. This hypothesis is supported by the acute reduction of platelet count immediately after AVR. From their observation, the platelet level will slowly recover in the second postoperative week. The toxic effect cannot be eliminated by rinsing the valve in similar manner such as glutaraldehyde-fixed bioprostheses.[16] All these researches were not associated with thromboembolic or hemorrhagic complications. However, a research done by Beholz S. and associates which published in 2010 revealed none of the patients reported to have severe thrombocytopenia as a compli-

cation. Their study involved 256 patients.[17] Further investigation with larger sample size is required to prove this phenomenon since most of the previous researches encountered with transient thrombocytopenia involved small sample size (less than 50 patients).

The technique of valve implantation at the supra annular position increase the effective orifice area with the implantation of larger size prosthesis. This results in positive haemodynamic outcome and reduces the valve related mortality. This was the reason why in the previous study concluded that stentless bioprosthesis is recommended for patient with severe aortic valve disease associated with small aortic annulus.[18, 19] The echocardiographic findings in the early postoperative course demonstrated excellent hemodynamic outcome, showed by reduction in the mean transvalvular pressure gradient from 26.5 ± 11.90 mmHg to 15.25 ± 10.11 mmHg. AVA was also found to be increased in patients having stenosis from 0.74 ± 0.23 cm2 to 1.50 ± 0.57 cm2 and it remained stable thereafter. For the patients having aortic regurgitation, there was no data available of the aortic valve annulus size before implantation.

Although the observation was insignificant, this observation is supported by the results from other studies.[7, 18, 20] The study done by Beholz S. and associates in Charité-University Medicine, Berlin, Germany showed the improvement in the mean transvalvular pressure gradient and AVA. Their study involved a total of 256 patients between July 2004 and September 2006 in nine European institutions. The result found the reduction in mean transvalvular pressure gradient from 42.3 ± 20.2 mmHg preoperatively, 6.5 ± 3.8 mmHg at one month, and 6.7 ± 4.1 mmHg at 12 months. The AVA was improved from 0.78 ± 0.35 cm2 preoperatively to 1.90 ± 0.56 cm2 at 1 month and 1.89 ± 0.56 cm2 at 12 months.[21]

Based on current observation, the result of LVEF demonstrated a reduction from 65.75 ± 6.30 % to 61.25 ± 11.84 % within 5 months postoperatively. Current result for LVEF was contradicted by some other researches. Their researches showed the improvement in LVEF after FS valve replacement (21, 20). Although our study demonstrated reduction in LVEF, the mean LVEF was still in normal range. Further follow up needed to monitor LVEF in those patients receiving FS valve.

The mean cross-clamp time for isolated valve replacements was 80.50 ± 21.92 minutes and 147.00 ± 26.87 minutes with associated procedures. However, previous researches contradicted our observation. Many of the researches demonstrated a significant reduction in cross clamp time (CCP) with Freedom Solo valve.[10, 22, 23] For example, research done by Dimitrios IC and associates at University of Athens, Athens, Greece showed the cross clamping time was 52.71 ± 11.94 minutes for isolated FS aortic valve implantation and 80.46 ± 28.33 minutes with concomitant procedures. Their research involved a total of 128 patients between October 2006 and February 2010.[23] The possible reason for prolong cross clamping time in our study is due to our cautious and meticulous implantation procedure resulted in no advantage over implantation time.

During the study period, one patient died 4 months after the operation due to community acquired pneumonia. The death was not associated with postoperative complication. There were no paravalvular leakages or transvalvular regurgitations identified in other patients during the follow up period. This observations were supported by other researches. Mean echocardiographic data collected in short and mid-term by different studies show a low number of paravalvular leakage and aortic regurgitation.[7,16,17] However, early complications did occur in 2 patients. One patient had left hand ischaemia and low cardiac output syndrome 20 days after the operation and the other one had hemorrhage from the sternal wire puncture site a day after valve replacement.

In the later, the previous median sternotomy was re-explored and bleeding from a branch of the right internal mammary artery was clipped and cauterized. The possibility of bleeding occurrence was less likely due to postoperative thrombocytopenia. This is because the level of patient's platelet count was still in normal range in the first postoperative day (>100x109/L).All the patients were treated successfully and discharged home well. There was no other bleeding complication observed and no platelets transfusion was required. Adverse valve related events such as endocarditis, reoperation, embolism or structural valve deterioration did not happen in this group of patients.

Conclusion

In conclusion, the FS stentless valve demonstrates good short-term clinical and hemodynamic outcomes. However we encountered severe thrombocytopenia in patients having FS aortic valve replacement though no bleeding complication occurred. Further study needed to clarify the mechanisms and consequences of platelet reduction after the implantation of the FS bioprosthesis. Our result was not significant enough to establish the conclusion since there were some limitations in this study. The main limitation of the study is the small number of the subject. This is due to low frequency of the FS bio prosthesis valve implantation in our department. Larger sample size and longer study period should be established to support our conclusion. Furthermore, our research lack of control group. Thus, no comparison between FS bio prosthesis valve and other valve can be evaluated. Further study regarding the usage of FS bio prosthesis in Malaysia should be done to establish the advantages and its complications.

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