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Research Articles

Case Report

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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*

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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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Self perception and quality of life of adolescents who had undergone open-heart surgery due to cyanotic congenital heart disease in their infancy

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Summary

Aim: To assess the quality-of-life of the teenage patients who had undergone open heart surgery because of cyanotic heart disease during their infancy together with their parents and to compare their self-perception to that of the physically healthy control group.

Material and Method: This study includes 53 patients who had undergone operation for cyanotic congenital heart disease in İstanbul University, Institute of Cardiology between 1989 and 1994. The relatives and the patients were informed with a consent form approved by İstanbul University, Cerrahpaşa Medical Faculty, Clinical Studies, Ethics Commitee (Decree no. D-005, Date: 11-10-2009). Group 1 was the healthy control group (15 patients, median age: 19 years 8 months), Group 2 included patients with single ventricle who had undergone Fontan procedure (20 patients, median age: 19 years 6 months; 10 of them had tricuspid atresia, 5 of them had pulmonary atresia with intact ventricular septum, 3 of them had double inlet left ventricle, 1 of them had double outlet right ventricle, 1 of them had ventricular septal defect and pulmonary atresia), group 3 included patients who had undergone operation for congenital cyanotic heart disease (33 patients, median age: 19 years 2 months; 18 of them had transposition of the great arteries, 10 of them had tetralogy of Fallot, 2 of them had complete atrioventricular canal defect and pulmonary stenosis, 2 of them had double outlet right ventricle, 1 of them had pentalogy of Fallot). In this study, the quality of life and self perception inventories were used. The quality of life inventory was completed by patients, healthy adolescents and their parents seperately. The self perception inventory was completed only by the patients and healthy adolescents. The comparison of age and self perception scores between the groups was carried out with unidirectional analysis of variance (ANOVA) and the multicomparisons with LSD (Least Significant Difference). Since the quality of life variable did not have a normal distribution, the comparions were carried out with Kruskal-Wallis nonparametric ANOVA test and the multicomparisons were carried out with Dunn's test.

Results: There was not a significant difference between the groups in terms of age and sex. In the quality of life scale (QOLS), for the replies to related questions, a significant difference was determined between the groups. The replies of group 2 and 3 about quality of life of both the children and the parents were far more negative when compared to those of the control group. When the groups were compared via multiple comparison tests, there was no significant difference between group 2 and 3. The replies of the parents regarding their children's quality of life were statistically more negative than those of their children ($p<0,001$). Within the self perception scale, there were significant differences in terms of social acceptance, behaviours in relationships and general self perception ($p=0,03$, $p=0,03$ and $p=0,01$; repectively) between group 1 and 3. The most significant difference that was detected between group 1 and 2 was about behaviours in relationships ($p=0,04$).

Conclusion: With the help of developing technology and surgical experience, many complex cyanotic heart diseases are treated successfully and most patients reach puberty. However the responses for quality of life and self perception paremeters of this group of patients are more negative than those of the control group. Therefore, these adolescents and especially their parents may need psychosocial support.

Keywords: Adult, congenital heart disease, cyanosis, quality of life, self-perception profile

Introduction

Significant complications of congenital heart diseases which occur with a rate of 8-12 per 1000 live births include congestive heart failure, hypoxia and cyanosis. Cyanosis appears when reduced hemoglobin in cutaneous veins increases above 5 g/100 mL. Congenital heart diseases leading to cyanosis include transposition of the great arteries, Fallot tetralogy, total anomalous pulmonary venous return, tricuspid atresia, pulmonary atresia with intact ventricular septum, hypoplastic left heart syndrome, truncus arteriosus, single ventricle, double outlet right ventricle and atrial isomerisms. Early diagnosis of these complex heart anomalies and management in the neonatal period or in infancy by assistant and/or full correction operations have vital importance.

Low oxygen level in the blood and side effects of cardiopulmonary by pass affect many organs negatively including mainly the brain.[1,2] While full correction operations are performed for many complex congenital heart anomalies, Fontan operation which is known as an assistant intervention is performed in patients with single ventricle. With Fontan operation systemic venous return is directed to the pulmonary system and single ventricle is provided to maintain systemic circulation. Patients who have undergone Fontan operation should be evaluated separately form other congenital heart diseases because of problems including metabolic and hormonal factors and low saturation rate.

The World Health Organization defines health as a state of complete physical, mental and social well-being. Studies for definition of complete well-being has introduced the concept of quality of life and quality of life has been briefly defined as an individual's perception of their position in life in the context of the culture and value system in which they live.[3,4] In the end of the last century, health-related quality of life which emphasizes individual point of view gained importance in the evaluation of data related to health, clinical studies and results of new treatments. It was reported that interventions to improve quality of life in the early ages would be beneficial for prevention of or protection from problems of quality of life which would occur in the future and would guide the physicians in directing treatment.[5] The term "health-related quality of life" which is defined as perception of the effects of a disease and its treatment on the patient by the patient shows variance according to the patient's individual characteristics.[6]

Our aim was to emphasize the physical and psychosocial functionalities of adolescents who had undergone open heart surgery because of congenital heart disease in infancy together with their parents, to determine the level of self perception and enlighten the subject of what could be done in case of negativities.

Material and Method

53 patients who were operated because of congenital cyanotic heart disease between 1989 and 1994 in İstanbul University Institute of Cardiology were included in the study. 15 individuals who had no complaints, whose physical examination was normal and who were healthy physically (8 males, 7 females; mean age 19 years 8 months) were included as the control group (group 1). 20 patients who had undergone Fontan operation (10 males, 10 females; mean age 19 years 6 months) constituted group 2 and 33 patients who had been operated because of other cyanotic heart diseases (20 males, 13 females; mean age: 19 years 2 months) constituted group 3.

Assistant interventional methods and operations performed before Fontan operation in patients who had undergone Fontan operation and the ages at the time of these interventions; balloon atrial septostomy in two subjects [1 day old(1), 2 days old(1)], Glennshunt in 11 subjects [0-1 years old(6), 1-2 years old(4), 2-3 years old(1)], Blalock-Taussig shunt in 5 subjects [4 months old(1), 1-2 years old(3), 2-3 years old(1)], pulmonary band in 1 subject (1 month old).

Assistant interventional methods and operations performed in patients with other congenital cyanotic heart diseases and the ages at the time of these interventions; balloon atrial septostomy in 4 subjects [1 day old(2), 2 days old(2)] and Blalock-Taussig shunt in 7 subjects [0-1 months old(4), 2 months old(2), 4 months old(1)]. While classical Fontane was performed in 5 of 20 patients who had single ventricle anomaly (right atrium-pulmonary artery anastomosis), total cavapulmonary anastomosis was performed in 15 subjects. 7 of these were performed as intracardiac (lateral) tunnel and 8 were performed as extracardiac tunnel. Tube grafts were used in 3 patients and autologous pericardium was

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used in 5 patients for extracardiac tunnel. In 33 patients with other complex cardiac anomalies, complete correction operations (Senning, Jatene, Rastelli etc.) were performed according to the type of the disease. While the time of cardiopulmonary by pass was found to be 56,55±16,02 minutes in group 2, it was found to be 83,88±33,64 minutes in group 3. There was a significant difference between the two patient groups in terms of cardiopulmonary by pass time (t=3,397; degree of independence (d.i) =51; p<0,001).

Patients were randomly selected during routine outpatient follow-up. Adolescent patients, physically healthy adolescents and their parents completed the Quality of Life Scale form seperately. The Self perception Scale form was completed only by the adolescent patients and physically healthy adolescents. Different question groups in both subjects were responded in 15 minutes. Approval was obtained from the İstanbul University Cerrahpaşa Medical Faculty Clinical Research Ethics Committe (decision number: D-500, Date: 11-10-2009). The patients and relatives were informed with the informed consent form.

Quality of life inventory

For evaluation of quality of life the Quality of Life Inventory Adolescent form which was developed by Varni et al.[7] in 1999 and which was examined afterwards in terms of validity and reliability for the Turkish language was used[8,9]. The inventory consists of four parts which question physical, emotional, social and academic functionality. The part of physical functionality contains 8 questions, the parts of emotional functionality, social functionality and academic functionality contain 5 questions each. These questions are directed to the children and their parents. For answers likert type answer scale with five options is used (0= never, 1= rarely, 2= sometimes, 3=frequently, 4= always). In the part of physical functionality, score of the 8 items are summed and divided to 8 to obtain the total score of physical health.

Total scores are obtained for each area by summing of the scores of 5 items in each part including emotional functionality, social functionality and school-related problems which constitute psychosocial health and dividing to five which is the total number of items.[10]

Self-perception profile for adolescents (SPPA)

This is the form arranged for adolescents derived from the self-perception profile for children which was developed by Harter.[11] In the English source of the self-perception profile for adolescents, alpha coefficient which expresses self-consistency ranges between 0,78 and 0,92 according to dimensions.[11] In the study performed by Şahin and Güvenç[12] in which SPPA was adapted to Turkish, alpha coefficient was found to be 0,88 and the reliability coefficient for test-retest which was performed in a sample group consisting of 130 individuals with intervals of three weeks was found to be 0,87. In another pilot study performed in 197 high-school students in Turkey using SPPA, the reliability coefficients for test-retest (with an interval of 2 weeks) were found to range between 0,75 and 0,87 and for self-consistency between 0,77 and 0,90.[13]

Self-perception profile for adolescents is a likert-type scale consisting of 45 questions. It consists of 5 close questions mainly in 9 subscales. Two different sentences defining two different personalities are contained in the items. The person filling out the profile is asked to decide which one of the two groups he/she belongs to and to mark if this sentence is fully or partially appropriate for himself/herself. However, it should be kept in mind that psychological disorder is not meant when mentioning negativity, because there is no psychiatric disorder like “low self-perception syndrome”. In answers given to self-perception scales, a score of 1means not perceiving oneself valuable, a score of 2 means perceiving oneself partially valuable, a score of 3 means perceiving oneself valuable and a score of 4 means perceiving oneself very valuable. These subscales and what they measure are summarized below:

Academic sufficiency: This subscale measures the self-perception of children about academic success and how intelligent they perceive themselves. Social acceptance: This subscale measures to what degree the children are accepted, liked and loved by their peers.

Athletic sufficiency: This subscale measures the self-perception about sportive success and athletic sufficiency.

Physical appearance: This subscale measures how satisfied one is with his/her physical appearance and body.

Job sufficiency: This subscale evaluates the ability of the person in his/her job, if he/she is always ready to perform part-time jobs and their belief in how well they perform their jobs.

Romantic attraction: These questions measure if the person is found attractive by the individuals he/she likes and if he/she can go out with people he/she likes.

Behaviour in relations: This subscale measures how satisfied the person is with his/her own behaviour and the self-perception how well he/she does what he/she is expected to do or what is right.

Intimate friendship: This subscale measures the self-perception about the ability to institute intimate friendship where the person can share personal thoughts and secrets.

General self-value: This subscale measures how much the person loves himself/herself and how he/she is satisfied with his/her life. The person's judgements related to his/her values are evaluated. Even evaluation of this subscale alone is important.

Statistical analysis

In assessment of the data, SPSS (SPSS Inc., Chicago, IL, USA) 16.0 for Windows was used. The distribution of frequency of the groups by gender was assessed using chi-square test. In comparison of cardiopulomonary by pass times of the two patients groups who had undergone operation, student's t test was used. In comparison of the scores of age and self-perception, single-tail analysis of variance (ANOVA) was used. Multiple comparisons were performed using LSD (Least Significant Difference). Since the variable of quality of life did not have a normal distribution, comparisons were done using Kruskal-Wallis nonparametric ANOVA test and multiple comparisons were done using Dunn test. In all hypothesis tests, a p value of <0,05 was considered to be significant.

Results

No statistically significant difference was found between the groups in terms of age and gender (p=0,56 and p=0,73, respectively). When statistical comparison of the answers to the Quality of Life Scale questions between the groups was done using Kruskal-Wallis nonparametric ANOVA test, a significant difference was observed in all questions both in the form for the child and the form for the parents (Table 2). In comparison of the groups using multiple comparison test of Dunn, a significant difference was observed between group 1 and group 2 and group 1 and group 3 (p<0,05). No significant difference was found between group 2 and 3 (p>0,05). The approaches of the parents in the answers to questions about quality of life of their children were observed to be much more negative (p<0,001).

In the answers of the adolescents to the questions about self-perception, no significant difference was found between the groups except for general self-perception (p=0,05) using single-tail variance analysis (Table 3). However, significant difference was observed especially between group 1 and group 3 in terms of social acceptance, behaviour in relations and general self value (p=0,03, p=0,03 and p=0,01, respectively) using multiple comparison test LSD. The only significant difference between group 1 and group 2 was observed in behaviour in relations (p=0,04).

Discussion

Dysfunctionality observed in adolescents who had congenital heart disease and who had undergone open heart operation during infancy for this reason is an issue which should be emphasized. Although the patients tend to evaluate their own behaviour in a similar way to healthy adolescents, their parents and others evaluate the patients' quality of life negatively compared to the healthy population. The reason for this is the fact that families and especially mothers are emotionally pessimistic from the first day with the thought that their children have chronic heart disease and observe them differently in each stage of their lives.[14] Recent neurodevelopmental studies on children with congenital heart disease have evaluated the problems which these patients and their families experience by assessing not only intellectual functions, but also psychosocial adaptation and quality of life.[14,22]

With the advance of surgical notion and experience in parallel to the technology in the last 30 years, the baby who undergoes increasing number of heart operations each year grows, starts school life and even reaches adolescence.[15] In patients with complex heart

anomalies, a need for improving quality of life in the ones who survive after operation has become prominent.[16,17] All patients are exposed to psychological stress caused by having chronic cardiac disease for years.[18] Although an increase in the diagnoses of attention deficit and hyperactivity disorder has been observed in school-age children with cardiac disease in many current studies, the thoughts of the teachers and parents are omitted especially in evaluation of academic success.[19,20] The parents who observed each stage of their children were also included in our study and their answers revealed that they were more pessimistic about quality of life of their children with chronic disease. Therefore, the patients should be evaluated together with their parents as a whole.

Another significant point is the fact that published studies were focused on small patients groups or patients with a single cardiac problem.[21,22] Because of the dynamic nature of growth during infancy and childhood the validity of prediction assessments obtained during this period is limited.[23] Therefore, our study groups were consisted of adolescents who had just completed their childhood. Evaluation of neurodevelopmental outcome of children with congenital heart disease requires long-term follow-up during school period and afterwards to understand the significance and depth of the problems. This subject was addressed in long-term studies performed in 60 pediatric patients who had undergone arterial switch operation (Jatene) because of transposition of the great arteries in different periods by the same study group.[24,25]

In the study performed in patients with ages ranging between 7,9 and 14,3 years, deficiencies were observed in areas of attention, motor and cognitive functions, academic success, language, speech, neurological development and even social functionality in 55% of the patients.(24) This rate is two fold higher than the rate (26%) found in evaluations performed at the mean age of 5,4 years.[25]

Children with congenital heart disease carry a risk of deficiency in personal and social ability required for a healthy daily life. Majnemar et al.[26] reported that children with congenital heart disease aged 5 years old experienced problems in terms of personal care and social cognition using pediatric functional independence measurement. Shillingford et al.[27] reported that 49% of the children received supportive academic service and 15% were placed in special classes in a study they performed in children with complex cardiac anomaly aged between 5 and 10 years old.

It should be kept in mind that evaluation of satisfaction of the person may change, since the desires of the child changes as the age gets older. On the other hand, the severity of congenital heart disease can not predict quality of life. For example, Ternestedt et al.[28] showed that quality of life was better in patients with Tetralogy of Fallot compared to patients with atrial septal defect in a long-term follow-up study. It was concluded that the approach of social environment and family to the ill child can be efficient in the sociocultural frame.

In our study, when we examined quality of life in adolescents and in their parents in terms of physical health and psychosocial health (emotional and social functionality, school life), unfavorable findings were determined in all of them compared to physically healthy adolescents. This shows that these patients and their families lack quality of life.

When the answers to the questions of self-perception of adolescents who had undergone open heart surgery years ago were examined, unfavorable differences were observed especially between healthy adolescents and patients with cyanotic cardiac disease excluding single ventricle in terms of social acceptance, behaviour in relations and general self value. Although cardiac problems of patients with single ventricle who had undergone Fontan operation are more severe, more favorable self-perception compared to other cyanotic cardiac diseases may be attributed to the fact that cardiopulmonary by pass times of the patients with single ventricle were shorter compared to the patients with other cyanotic cardiac diseases. Most of the patients are conscious about their state. Because of some positive or negative comparisons in the society the relations of these patients with the environment are disrupted and they lose their self value. Therefore, we can list the contributions to daily life by measurement of quality of life and self-perception in these patient groups:

The possibility of evaluation of the patient by the team performing the clinical follow up not only by car-

diologic measurements, but also in a biological, psychological and social integrity.

Perception of the patient that he/she is understood and considered important by the physicians and thus strengthening the sense of mutual trust.

Early detection of possible need for psychiatric assistance in accordance with unfavorable answers determined by the scales and referral to adolescent psychiatry for assistance.

One of the most notable findings of our study is the fact that the traces of anxiety in the psychological life of the parents caused by a vital health problem experienced by children during the early period of their lives persist even years have passed. According to this result, the family which is the first circle of environmental factors should be included in the process of medical follow-up. In addition, the fact that the parents reported more unfavorable answers compared to the adolescents on anxiety about life is such a significant and interesting subject which can not to be fictionalized and which should be examined in detail in an independent study. The psychological therapy of these patients should be planned in the context of the family.

On the first step, supportive groups can be formed by bringing families together under guidance of experts on the subject. Family therapy should be performed in patients who need further support. As a result of the data we obtained in our study, it is clear that pediatric and adolescence psychiatrists should play an active role in the follow-up of the adolescents in the patient group, because low scores of self-perception and quality of life may be signs of significant psychiatric disorders including depression and anxiety disorder. The collobaration which will be instituted between the clinics in this context is vital in terms of physical and psychological health of the adolescent. We hope that these data we obtained will be a step for more detailed studies which will be performed on the subject in the future.

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Clinical outcomes after drug-eluting stent implantation for unprotected left main coronary artery disease

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Summary

Objective: Stenosis in the unprotected left main coronary artery (ULMCA) is considered a standard indication for surgical revascularization. Some studies have demonstrated that stenting of the ULMCA is safe and feasible in selected patients. Drug eluting stents (DES) have been shown to be superior to bare metal stents (BMS) in reducing restenosis and major adverse cardiac events (MACE) both in-hospital and at follow-up after treatment of ULMCA disease. Several studies showed that the mid-term prognosis of patients with left main stenting is good, but most of them are limited by small populations and the availability of mid-term results. Thus, we sought to evaluate the very long term impact of DES vs BMS in a large cohort of patients undergoing stent implantation for ULMCA disease in our center.

Material and Method: Between June 2002 and June 2008 a total of 354 consecutive patients with ULMCA stenosis were treated with percutaneous coronary intervention with BMS (53 patients) or DES (301 patients) implantation. A multivariable adjustment was provided in order to account for baseline differences between groups.

Results: The average clinical follow-up was 551±512 days. Overall, MACE rate was significantly lower in the DES group (16.6% vs 26.4%, P=0.02). The beneficial effect was driven by a reduction of death (6.0% vs 9.4%, P=0.11), MI (2.7% vs 3.8%, P=0.33) and target vessel revascularization after DES implantation (9.0 % vs 15.1%, P=0.11). After correcting for independent predictors of adverse events, the adjusted hazard ratios (HRs) for the risk of mortality and myocardial infarction after DES implantation relative to BMS implantation were 0.99 (95% CIs 0.30-3.21, P=0.98) and 0.59 (95% CIs 0.01-3.45, P=0.56), respectively. The adjusted HR for two-year MACE was 0.50 (95 CIs 0.25-1.02), P=0.056, mainly driven by a statistical significant reduction of TVR (HR 0.30 [95 CIs 0.11-0.82], P=0.018].

Conclusion: Patients presenting with ULMCA disease, who are treated with DES have a significant reduction in the rate of target lesion revascularization with no increased risk of death or myocardial infarction.

Keywords: Stroke, bare metal stents, drug eluting stents.

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Introduction

Among the inflammatory molecules, the role of C-reactive protein (CRP) has been deeply investigated in the last few years and its importance as prognostic marker in patients with coronary artery disease is now quite clear,[2,3] while less is known about inflammatory cytokines, which are also involved in the pathophysiology of atherosclerotic plaque.[4,5] The authors studied macrophage colony stimulating factor (MCSF), a growing factor involved in the proliferation and differentiation of macrophages, inflammatory cells with a central role in plaque genesis and destabilization. 6-8 The aim of this study was to determine whether MCSF serum levels, measured during the acute phase, may be a useful marker to predict short term outcome in patients with ACS.

Material and Method

The authors studies 74 consecutive patients who were admitted to the Intensive Coronary Care Unit of the University of Palermo (Italy) for ACS, 48 men (65%) and 26 woman (35%), mean age 66 12 years (range 46-87). According whit electrocardiographical (ECG) presentation, patients were distinguished as those with ST elevation myocardial infarction (STEMI,N.=35) and those with non ST elevation myocardial infarction (NSTEMI, N.=39). The study protocol was conforming to the ethical guidelines of the Helsinki Declaration and all subjects gave their informed consent to participate to the study. At admission all subjects underwent a complete medical examination and the Killip's class was determined (according with the detection of clinical signs of left ventricle dysfunction).[9] Moreover patients were asked about their past medical history and cardiovascular risk factors. Among the risk factors were: the presence of family history of cardiovascular disease (in a first- degree relative, younger than 55 years), hypertension (systolic or diastolic blood pressure respectively higher than 140 mmHg or 90 mmHg or the use of antihypertensive drugs), diabetes mellitus (fasting glucose plasma concentrations higher than 126 mg/dL or pharmacological therapy with oral hypoglycaemic drugs or insulin) smoking habits, obesity (body mass index [BMI] >30 kg/m²) and dyslipidemia (triglycerides >200 mg/dL, total cholesterol >200 mg/dL, LDL-C >130 mg/dL, HDL-C <40mg/dL in males and <50 mg/dL in females).10 Moreover, on admission a venous blood sample for the determination of MCSF, CRP and between MCSF and CRP concentrations were drawn. Among patients with STEMI 20 underwent primary percutaneous coronary intervention (PCI, 2 unsuccessful procedures), 7 were treated with thrombolysis (2 underwent rescue PCI) and 8 with medical therapy (because previous treatments were not applicable). Patients with NSTEMI were initially treated with medical therapy and then, if not contraindicated, coronary angiography was performed . Among patients with patients with NSTEMI: 22 underwent PCI, 7 underwent CABG and in 10 other patients there was no indication for revascularization. During their hospital stay, patients underwent echocardiography (Siemens Sequoia machine) and ejection fraction (EF) was quantified by biplane Simpson method.[11] Coronary angiography was performed in 84% of patients (angiographer Philips Integris 2000), according to ESC PCI guidelines.[12] Coronary artery stenosis was considered to be significant if 50%; subcritical if between 60% and 70% and critical if 70%. The degree of coronary angiography (QCA).[13] Patients were divided in 2 subgroups according to the severity of coronary artery: with one vessel disease and with multivessel disease. Clinical end points were short term outcomes in terms of cardiac death, recurrence of infarction or angina (pain similar in quality as the pain resulting in the presenting ACS, ECG changes).Two subgroup were identified according to the occurrence or not of adverse events during in- hospital stay.

Assays

Sera were obtained from blood within 30 minutes of venipuncture by clotting centrifugation at 4000 rpm for 10 min. Samples were aliquoted and frozen at -70 °C until assay. The laboratory measurements were performed by personnel unaware of the clinical data. Plasma MCSF concentrations were measured using a commercial enzyme- linked immunoassay (human MCSF, Quantikinine R&D system, Minneapolis, MN).

The sensitivity of the assay is 20 pg/mL. Total cholesterol, triglycerides and high density lipoprotein (HDL)- cholesterol were quantified by standard enzymatic- colorimetric methods, low density lipoprotein (LDL)- cholesterol was calculated by the Friedewald formula and fibrinogen with the Claus method. Fi-

brinogen levels were considered to be normal between 200mg/dL and 400 mg/dL. The levels of CRP in the serum samples were determined by a high- sensitivity ELISA kit (IBL, Hamburg, Germany). I troponin was determined daily and peak value was considered (Luminescent immunometric reaction, Ortho- Clinical Diagnostic method).

Statistical analysis

Statistical analyses were performed using the Stat view Program (Abacus Concepts Inc.)Values were given as number and percentage or mean SD. T student's test was used to compare values of patients and controls; x^2 test was used to compare STEMI and NSTEMI patients. The patients were divided in different subgroup stratified by the severity of coronary artery disease (2-3 vessel vs one vessel) and in hospital cardiac events (events vs no events): t student's test was used to patients. Differences were considered to be significant when obtained a P value <0.05. To correlate MCSF levels with CRP, the Sperman's rank correlation coefficient was used to compare these different subgroups of patients. Different subgroups of patients. Differences were considered to be significant when obtained a P value <0.05. To correlate MCSF levels whit CRP, the Spearman's rank correlation coefficient was used. A multiple regression analysis was performed to asses whether MCSF was a variable independently related with adverse events.

Results

Table I shows baseline characteristics of patients and differences among the subgroups with STEMI and NSTEMI. There was not a significant difference be-

Table I	All patients (N.=35)	STEMI (N.=35)	NSTEMI (N.=39)
Age (years)	66 12	64	68
Sex (N. and %)	48 (65%)	24 (32%)	24 (32%)
	26 (35%)	8 (11%)	18 (24%)
Hypertension	47 (64%)	25 (71%)	24 (62%)
Obesity	19 (26%)	9 (26%)	10 (26%)
Diabetes mellitus	23 (31%)	11 (31%)	12 (31%)
Current smokers	28 (39%)	14 (40%)	14 (36%)
Family history of CAD	38 (51%)	16 (21%)	22 (56%)
Dyslipidemia	23 (31%)	10 (46%)	12 (33%)
Total chol (mg/dL)	201.94 95.32	211.03 133.48	197.25 102.49
HDL chol (mg/dL)	45.94 15.55	43.61 14.75	48.36 16.28
LDL chol (mg/dL)	155.85 55.12	134.91 46.72	174.7 56.33
Triglycerides (mg/dL)	159.37 148.29	131.85 53.22	186.89 201.04
Troponin (ng/mL)	24.93 18.99	31.07 10.93	17.7 6.25
MCSF (pg/mL)	332.96 96.00	326.65	297.15 110.43
Fibrinogen (mg/dL)	424.52 105.6	472.07 143.87	390.07 90.77
CRP (mg/L)	1.05 0.45	1.23 107.55	1.01 0.48
Killip's Class > II	17 (23%)	6 (17%)	11 (28%)
EF (%)	51 11%	53 11%	49 13%
2-3 vessels CAD	34 (46%)	15 (43%)	19 (49%)

tween STEMI and NSTEMI patients in MCSF and CRP levels (respectively 326.65 143.87 vs 297.15 110.4 pg/mL, P=NS; 1.23 0.48 mg/L,P=NS). A correlation was found between CRP and MCSF levels (P=0.05, Spearman rank =0.30). MCSF levels were significantly higher in patients with single vessel disease compared with patients with two or three vessels disease (233.61 128.29 vs 330.03 241.51 pg/mL, P=0.04) as well as CRP ones (0.60 0.22 vs 1.14 0.50 mg/L).As for the adverse events, among patients with STEMI: 5 died during in- hospital stay and 2 suffered from angina recurrence. Among NSTEMI patients, 4 deaths occurred, 3 recurrent anginas, and 1 re-infarction. Patients with in hospital fatal adverse events showed higher MCSF levels compared with those without adverse events (363.00 147.61 vs 251.00 186.69 pg/mL, P=0.03). CRP levels were also raised in subjects with in hospital adverse cardiac events ("events" vs "no events" 1.04 0.40 vs 0.97 0.50 mg/L, P=0.03). Multiple regression analysis showed that MCSF was a variable independently associated with adverse events (P=0.0520).

Discussion

Less is known about the role of other inflammatory molecules. MCSF is a cytokine involved in the regulation of proliferation and differentiation of monocytes and macrophages and released by the injured endothelium. This plays an important role in destabilising the atheromatous plaque and in triggering ischemia.[7,8,15] Previous studies already showed increased MCSF levels in patients with stable and unstable angina.[16,17]

Moreover, some authors observed how increased MCSF levels in patients with unstable angina may predict a worse prognosis during in hospital stay and in a mid to long term period.[16,18-21] This study confirmed the importance of MCSF as a prognostic marker in acute coronary syndrome with its levels higher in patients with worse in hospital stay and more diseased coronary vessel. Moreover, for the first time the authors have observed the abserved the absence of significant statistical differences of its concentrations between STEMI and NSTEMI patients.

This underlines how MCSF levels reflect the inflammation burden and not the amount of necrosis. Moreover, MCSF is a marker of inflammation, this finding reinforce the hypothesis that inflammation is the common pathway of ACS, which mainly differs in the degree of thrombosis, that may be occlusive and persistent leading to STEMI or transient leading to NSTEMI and not in the pathophysiological background.[22]

Conclusion

This study supports the hypothesis that inflammation is involved in the pathophysiology of ACS and that MCSF plays a novel and intriguing role, in predicting the patient's prognosis. In order to confirm this fascinating hypothesis further and extensive studies are needed.

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Experience With PTFE 'Ecoflon' (Russia) Vascular Grafts in Surgery of Aortoiliac Lesionse

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Summary

Objective: The choice of artificial conduit is issue of the day so far. The use of Dacron versus PTFE as a conduit in aortoiliac position is based on the preference of the surgeon. PTFE "Ecoflon" vascular grafts manufactured since 1994 may be used in surgery of aortoiliac lesions together with foreign analogues.

Material and Method: 197 executive patients with aortoiliac lesions were consecutively treated using linear or bifurcated PTFE "Ecoflon" vascular grafts. In-hospital (30-days) mortality, amputation rate, patency rate and complication rate were analysed in the early postoperative period. Primary patency, secondary patency, limb salvage, survival rates, infection complications and false aneurysms were assessed for estimate of long-term results. Histological study of distal anastamotic sites was performed in the patients with postoperative thrombotic events after re-intervention.

Results: 'Ecoflon' polytetrafluorethylene vascular grafts are highly biologically inert. This is confirmed by histological examination. Limb salvage, primary and secondary patency rates have demonstrated that PTFE "Ecoflon" vascular grafts provide long-term maintenance of adequate blood flow through bypass under favorable haemodinamic conditions. The rates of complications directly related to qualities of vascular conduit (graft infection, false aneurysms, bleeding from anastamotic sites) were compared with the data of published studies.

Conclusion: 'Ecoflon' PTFE vascular grafts are biologically inert prostheses, possessing structural porosity and no surgical porosity, with original arrangement of fibrils. Grafts can be sterilized using modern sterilization methods. In addition, they have favorable biomechanical properties (elasticity, extensibility, flexibility and durability). In our opinion, PTFE "Ecoflon" vascular grafts meet the requirements to "ideal vascular conduit" postulated by J.F. Vollmar in 1962.

Keywords: PTFE 'Ecoflon' vascular grafts, surgery of aortoiliac lesions, patency rate, limb salvage rate.

Introduction

The development of aortoiliac lesions surgery was impossible without creation and application of the synthetic vascular grafts because the use of autological materials or endarterectomy is limited or impossible. Since 1952, the Vinyon synthetic vascular grafts have been used in aortoiliac surgery.(1) The further progress of vascular surgery was closely connected with improvement of synthetic vascular grafts.

In the 50-60s of past century, the textile prostheses based on Dacron, Lavsan, Phthorlavsan, Terilen, Teflon and others appeared. In the 70s in USA, the "Gore" Company started the production of polytetrafluoroethylene (PTFE) vascular prostheses. Later on, repetition work of prostheses from PTFE was assimilated by several other companies like "Baxter", "Suler Vascutek", "Atrium", "B-Braun". However, their high cost limited their wide use in different countries. In the Russian Federation, the production of PTFE vascular conduit was started in 1994, when "Ecoflon" presented the first version of linear vascular grafts while bifurcate vascular grafts were presented in 1996. Nowadays, I.P. Dudanov et al. (2007)[2], A.G. Evdokimov et al. (2001)[3], P.O. Kasanchyan et al.(2001)[4], A.V. Maximov et al. (2006)[5], M.V. Melnikov et al. (2008)[6] have rich experience with PTFE "Ecoflon" (Russia) vascular grafts in aortoiliac lesions. They appreciated these grafts highly.

Analysis of published data concerning the use of different kinds of conduits in surgery of aortoiliac lesions has not shown any significant difference in outcomes depending on prosthetic material of conduits.[7] The use of Dacron versus PTFE as a conduit in aortoiliac position is based on the preference of the surgeon. The main important criterions of conduit quality are inertness, histocompatibility, resistance to infection and favorable biomechanical properties (elasticity, extensibility, flexibility and durability).

According to the Trans Atlantic Inter-Society Consensus II (TASC – II), the "gold standard" of primary patency rates at 5 years and at 10 years is from 87% to 91% and from 81% to 86%, respectively, in C type and D type of lesions. Primary patency rate is decreased in average by 10% in the patients with critical limb ischemia and/or the presence of femoropopliteal artery occlusion.[8,9] Despite the mortality rate following aorto-bifemoral bypass procedures decreased during the last decades, the patency rate did not change.[10] Furthermore, graft infection (mortality rate varies from 25% to 88%)[11], false aneurysms[12] and neointimal hyperplasia[13] did not diminish during last decades.

Material and Method

197 executive patients with aortoiliac lesions have been consecutively treated using linear or bifurcated PTFE "Ecoflon" vascular grafts at the vascular surgery department of I.I. Mechnikov Academy in the period between 2002 and 2010. The age of the treated subjects varied from 40 to 81 years, the age median was 60.5±20.5 years. Bilateral iliofemoral lesions were present in 121 patients (61.4%), unilateral iliofemoral lesions in 72 subjects (36.6%) and 4 patients had abdominal aortic aneurysm (AAA) without clinical signs of peripheral arterial disease (PAD). Males predominated in the study population (92.1%).

Indications for surgical intervention included aortoiliac occlusive disease with grade II (34.2%), III (51.3%) and IV (14.5%) chronic limb ischemia according to R. Leriche - R. Fontaine. Duration of disease varied from 6 months to 8 years. Ischemia worsened slower in the patients with II grade than in the patients with III or IV grade. Decompensation of low limb peripheral circulation during 1 year was found in more than 85% patients. Coexisting diseases were revealed in 181 (91.9%) patients. The leading of them were pathology of the cardiovascular system (170 patients) such as heart failure, ischaemic heart disease, previous stroke or TIA and hypertension. More than ¾ patients were current smokers and hyperhomocysteinemia (Hcy) was diagnosed in ¼ patients.

Aortoiliac lesions were treated primarily by one of the following techniques: aorto-bifemoral bypass (113), aorto-unifemoral or iliofemoral bypass (72) and AAA repair by linear vascular graft(4). One-third of operated subjects underwent profundaplasty in order to improve distal run-off.

In-hospital (30-days) mortality, amputation rate, patency rate and complication rate were analysed in the early postoperative period. The objective (treadmill exercise and ABI) and subjective (health questionnaires like Short Form 36 Health Survey (SF-36), Vascular Quality of Life Questionnaire, VascuQol) signs were assessed to define the success of the following vascular reconstruction in the early postoperative period.[14, 15]

The special emphasis was placed to the complications that might be connected with the vascular conduit quality such as incidence of early graft occlusion, severe intraoperative and secondary early haemorrhage, graft infection. Primary patency, secondary patency,

limb salvage, survival rates, infection complications and false aneurisms were assessed for evaluation of long-term results.

As factors negatively affecting the long-term results of such intervention we assessed the following: clinical stage of disease (intermittent claudication versus critical limb ischemia), quality of run off vessels, co-existing diseases, cardiovascular risk factors (smoking, dyslipidemia, chronic renal insufficiency, diabetes mellitus and others) and technical failures (uncommon sutures, widespread endarterectomy and others).

The telephone questioning, analysis of medical history, laboratory examination and imaging techniques were used in order to study the catamnesis. Additionally, ankle-brachial index (ABI) and toe systolic pressure (in patients with diabetes mellitus) were measured for evaluation of successful revascularization. Patency was assessed as per the guidelines by R.B. Rutherford et al. [16] Patency was determined by duplex ultrasound imaging and presence of shunt pulsation.

Material for histological examination was fixed for 24 hours in 10% formaldehyde solution. A standard protocol of tissues compression and dehydration in isopropyl alcohol was used for preparing microscopic slides. These samples were then embedded in paraffin. Hematoxylin-eosin was used for those sections to be investigated by light microscopy. The light microscopy was performed with original magnification of X100, X400. The invasion of connective tissue, grade of arterial wall sclerosis, degree and particular kind of chronic inflammation were assessed.

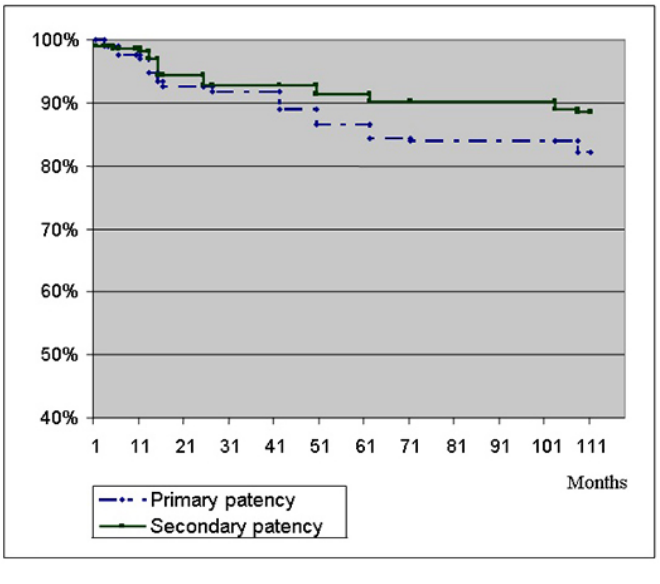
Patency rates were calculated using Kaplan-Meier life-table estimates. A long-rank test, Student's t-test and χ^2 test were used to compare the obtained results. A value of $p<0.050$ was considered as statistically significant. Statistical analysis was performed using SPSS 15.0 software (SPSS, Inc., Chicago, IL, USA).

Results

Complications in the intraoperative and early postoperative periods were observed in 15 patients (8.8%). The majority of them was represented by graft thrombosis – 9 patients (4.6%). The leading reasons for graft thrombosis were poor runoff and technical failures during the procedures. In six of them additional reconstruction of runoff vessels was carried out for revascularization. The early secondary haemorrhages were observed in 3 (1.5%) patients. The causes of them were technical failures. It is significant that haemorrhages from needle stitches observed in previous generations of conduits are not present in modern modifications. Three patients with trophic disorders developed deep wound infection involving the bypass. That required the removal of the infected bypass part. One patient was successfully treated by means extraanatomical shunting, and above-knee amputation was necessary in 2 patients. Six patients died at the hospital or within 30 days after operation. In-hospital (30-days) mortality was 2.9 %. The causes of death were coronary (myocardial infarction - 3) and cerebral events (stroke -1) and specific complications.[2]

The long-term outcomes were evaluated in 136 patients. Mean follow-up was 84.5±23.5 months. Primary patency rates at 1, 5 and 9-years of follow-up were 96.9±0.36%, 86.5±2% and 82.2±0.8%, respectively. Secondary patency rates at 1, 5 and 9-years of follow-up were 98.2±0.3%, 91.4±1.7% and 88.5±0.3%, respectively. (Fig.1) Multiple lesions of infrainguinal arteries ($p<0.01$), presence of critical ischemia ($p<0.05$) and young age of the patients ($p<0.05$) reduced the patency rate. Graft thrombosis was observed in 8 patients within a period of 15-18 months (4.1%) after surgery and in 8

Fig-1. Kaplan-Meier survival estimate primary and secondary patency rates of PTFE "Ecoflon" vascular grafts for aortoiliac lesions.



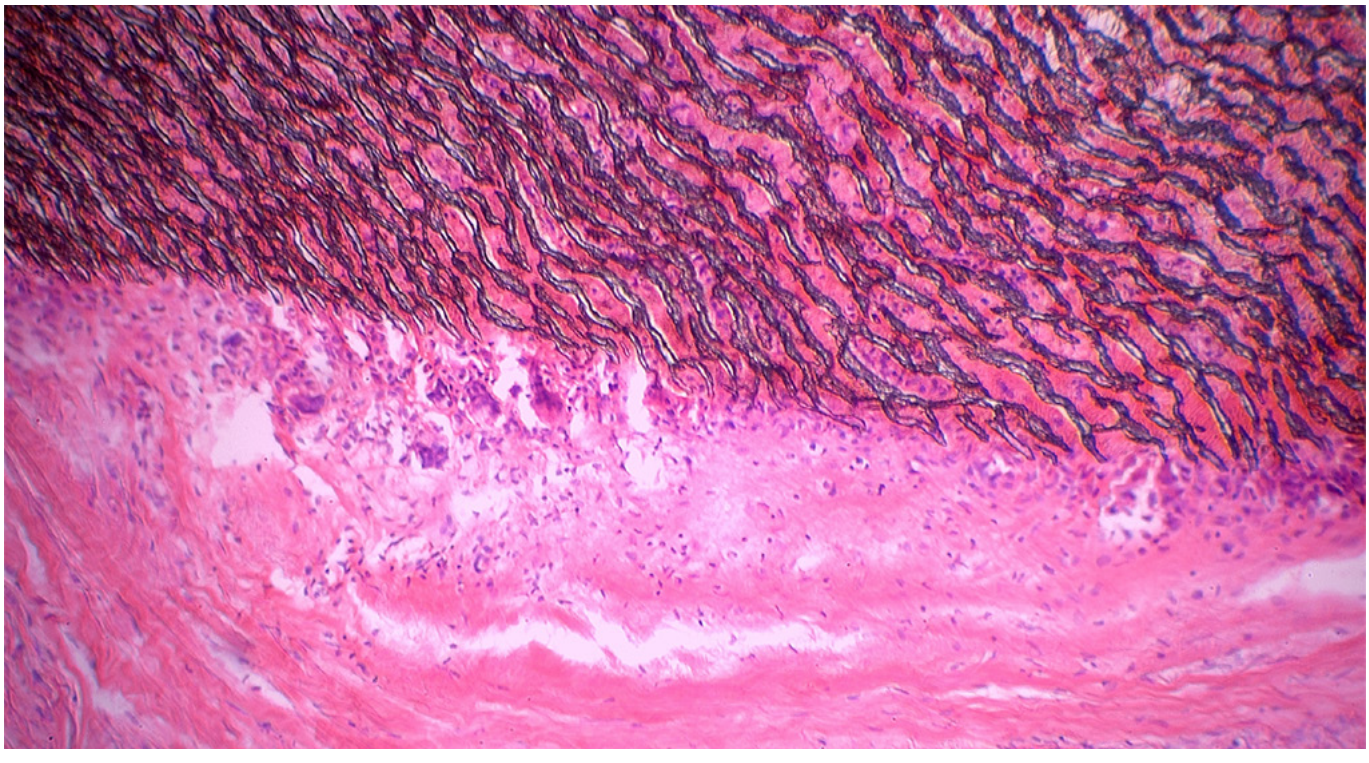
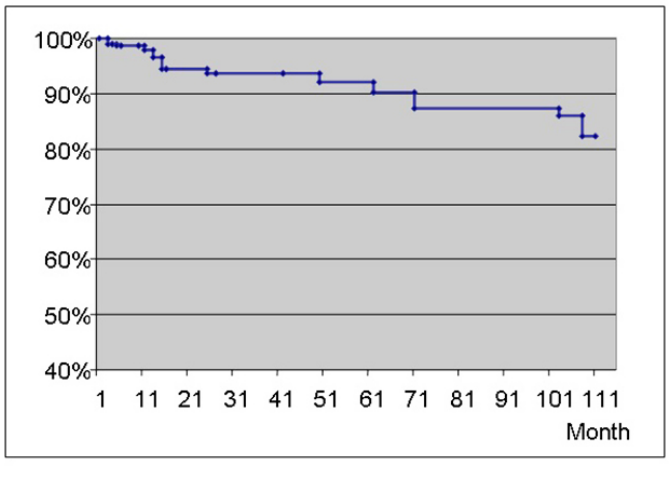


Fig-2. Light microscopy: PTFE "Ecoflon" graft 12 months after implantation in aortofemoral position. Complete coverage of outer surface of the graft with a layer of well-marked connective neoadventitial tissue without marked macrophage and neutrophil infiltration (Hematoxylin-eosin stain., original magnification x 400.)

patients in later terms.

The leading reasons for graft thrombosis in the persons aged 50 years and above were neointimal hyperplasia, elevated von Willebrand factor level (186.1±48.2% vs 144.1±37% in elderly subjects ($p<0.05$)) and C-reactive protein level (7.2±1.0 mg/l vs. 5.0±2.0 mg/l in elderly subjects ($p<0.05$)), as well as hyperhomocysteinemia (homocysteine levels = 17.6±4.2 nmol/l versus 10.7±3.2 nmol/l in elderly patients, respectively ($p<0.05$). The dominant reasons for graft thrombosis in elderly patients (persons aged above 50 years) were progression of atherosclerotic lesions in run-off vessels, elevated activated platelets count (28.5±4.5% vs 18.4±5.3% in young subjects ($p<0.05$) and aggregated platelets count (8.7±2.1% vs. 5.7±1.6% in young subjects ($p<0.05$).

Fig-3. Kaplan-Meier survival estimate limb salvage rate after aortofemoral reconstruction with PTFE "Ecoflon" vascular grafts.



False aneurysms of anastomotic site occurring due to low shear friction forces in points of turbulence, stagnation and "alienation" of stream, were successfully eliminated at three patients. Histological examination of graft walls obtained during repeated interventions (later than 1 year after primary surgery) demonstrated complete covering of the graft surface by a layer of well-marked connective neoadventitial tissue without neutrophil infiltration. Minimal or moderate cellular infiltrations were found in artery walls.

These cellular infiltrations were represented by lymphocytes and plasmocytes. Furthermore, the highest

possible accumulation of inflammatory cells was revealed in areas adjacent to the implant surface. Sometimes, single macrophages and gigantic cells were found. The detailed studies at our laboratory clearly demonstrated that the implant surface of each polyester fiber was surrounded by collagen fibers.

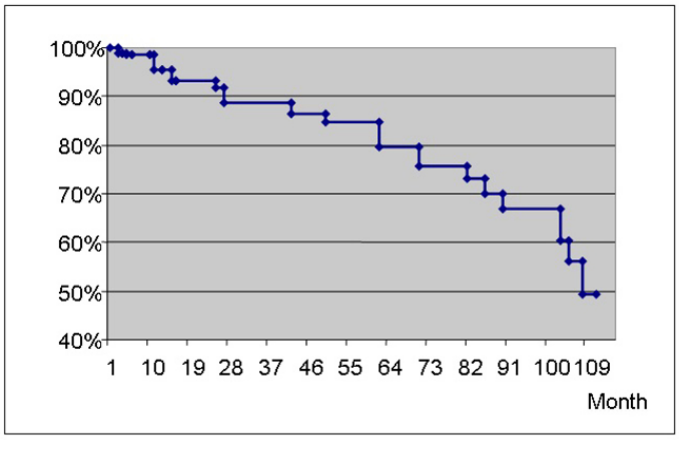
We also observed the invasion of fibroblasts and fibrocytes to the implant surface. (**Fig.2**) Limb salvage rates at 1, 5 and 9-years of follow-up were 97.9±0.4%, 92.1±1.24% and 82.4±3.2%, respectively. (**Fig.3**)

Survival rates at 1, 5 and 9-years of follow-up were 95.4±0.4%, 84.6±1.6% and 49.2±0.8%. (**Fig.4**) The leading reasons of death were coronary and cerebral catastrophes (68.2%) and oncology (12.2%).

Discussion

The PTFE "Ecoflon" vascular grafts may be used for bypass or prosthetics of any anatomical regions (except for coronaries and carotid arteries). Despite their high porosity, the "Ecoflon" vascular grafts due to optimal microporosity are not permeable even in arterial hypertension. Also, the high porosity provides for connective tissue invasion that led to formation of pseudointima connected with the body tissue. These vascular grafts do not require treatment with blood. These prostheses are softer and more similar to blood vessel than texture prostheses.

Fig-4. Kaplan-Meier survival estimate surveillance rate after aortofemoral reconstruction with PTFE "Ecoflon" vascular grafts.



Also, mechanical and physical characteristics play an important role in the quality of PTFE vascular grafts. [22,23] Our findings suggested that mechanical and physical properties of "Ecoflon" vascular grafts were comparable with vascular grafts produced by foreign companies. According to most researches, the adequate flexibility is one of the necessary criteria for artificial prosthesis. V.I. Koshev and co-workers (2007) studied a hydrodynamic flutter and antiflutter stabilization in the cardiovascular system. If the prosthesis does not support a pulse wave velocity the blood flow velocity is decreased. They documented that it could be a reason of acute occlusion.[24] Previous studies demonstrated that the pulse wave pressure transduction in "Ecoflon" vascular graft was comparable with human femoral artery.

Conclusion

Progress in vascular surgery is closely related to research in the field of synthetic vascular grafts. From these researches, a so-called ideal vascular conduit has to meet some requirements. "Ecoflon" PTFE vascular grafts are biologically inert prostheses with the original arrangement of fibrils and structural and no surgical porosity. Grafts may be sterilized by modern sterilization methods. In addition to mentioned characteristics, favorable biomechanical properties (elasticity, extensibility, flexibility and durability) of "Ecoflon" vascular grafts provide long-term maintenance of adequate blood flow through bypass graft.

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Minimally invasive ascending aorta replacement

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Summary

Abstruct: 56-year-old female patient weighing 80 kg was hospitalized to have an operation for aneurysmal expansion in ascending aorta (47 mm in TTE) detected in the examinations performed for complaints of chest and back pain. No other cardiological pathology was detected. Minimally invasive technique was preferred for the replacement of ascending aorta. Differently from aortic valve replacement, peripheral cannulation was preferred for arterial cannulation. Right brachial artery was explored with a 2-cm incision in axillary region from distal section of axillary artery and cannulated with 18 F peripheral artery cannula. A "two stage" venous cannula was inserted through right atrial appendix. During cardiopulmonary bypass for venous return, vacuum between 20 and 40 mg Hg was applied. Left atrial vent cannulas were also inserted via cardioplegia and left upper pulmonary vein. During the procedure, appropriate pump output (2.2-2.4 lt/min/m2) was established for the patient without any complication. Ascending aorta was replaced with vasculary graft of 24-mm diameter. Left ventricle was transeptally deaired through right ventricle in deep Trendelenburg position and external cardioversion was applied. After cardiopulmonary bypass was finished, brachial artery was primarily repaired with 5/0 polypropylene during decannulation.

Keywords: Minimally invasive, aorta replacement, cardiopulmonary bypass

Case

56-year-old female patient weighing 80 kg was hospitalized to have an operation for aneurysmal expansion in ascending aorta (47 mm in TTE) detected in the examinations performed for complaints of chest and back pain. No other cardiological pathology was detected. Minimally invasive technique was preferred for the replacement of ascending aorta. Differently from aortic valve replacement, peripheral cannulation was preferred for arterial cannulation. Right brachial artery was explored with a 2-cm incision in axillary region from distal section of axillary artery and cannulated with 18 F peripheral artery cannula. A "two

stage" venous cannula was inserted through right atrial appendix. During cardiopulmonary bypass for venous return, vacuum between 20 and 40 mg Hg was applied. Left atrial vent cannulas were also inserted via cardioplegia and left upper pulmonary vein. During the procedure, appropriate pump output (2.2-2.4 lt/min/m2) was established for the patient without any complication. Ascending aorta was replaced with vasculary graft of 24-mm diameter. Left ventricle was transeptally deaired through right ventricle in deep Trendelenburg position and external cardioversion was applied. After cardiopulmonary bypass was finished, brachial artery was primarily repaired with 5/0 polypropylene during decannulation.

The patient was taken into intensive care unit without any complication, then taken into normal clinical care on postoperative day one, and discharged in day five. There is no problem in the follow-ups as of postoperative week four.

Discussion

Aortic valve surgical interventions can be performed with minimally invasive techniques using partial sternotomies, parasternal incisions, mini-thoracotomies and transverese sternotomy incisions. Among these techniques, mini-sternotomy incisions which provide standard surgical appearance, stand out. Semi-sternotomy incisions limited to upper and lower ends, may be applied, and topographically, sufficient surgical opinion is obtained on the cardiac region to be intervened.

We are routinely applying aortic valve surgical interventions with sternotomy incision limited to upper end. Upper end mini sternotomy incision is appropriate for standard surgical equipment, and does not require additional technique investment. As sternum stability is protected, the risk for bone-related complications in postoperative period is less and patients have shorter recovery periods without any complications. Internal throcic artery injury is also a rare condition. Sufficient exposure can be obtanied for aorta surgery with short sternotomies less than 5 cm involving manubrium sterni.

Still, due to necessary cannulation procedure for installing cardiovasculary bypass connection, working area is reduced. When we started to do minimally invasive surgical intervention, we were preferring central cannulation for cardiopulmonary bypass. As cannulas narrow down the surgical area, search for alternative techniques became inevitable. Performing the surgical interventions with small incision without compromising the standard surgical technique is possible with some variations such as insertion of venous cannula through the incision used for mediastinum drain.

A major limitation related with limited sternotomy is the difficulties in positioning the heart. After removal of cross clamp, no manipulation can be performed for deairing of left ventricle apex or for cardioversion. For these, there are various alternative solutions: Transseptal deairing through right ventricle or external cardioversion with two cautery plates attached to the patient's back (in a direction consistent with cardiac axis) in preparation period before the surgery.

With the established solutions for the above mentioned limitations, the many benefits of minimally invasive surgery were understood better. Limited incision provides a fast healing period without complications especially in elderly patients as it protects sternal stability. It causes less pain, patient can be mobilized earlier and become self-sufficient. Smaller incision causes less bleeding and thereby, provides medical and economical advantages such as reduced transfusion requirement or shortened period for staying in intensive care unit or hospitalization.

By using alternative arterial cannulation and single venous cannulation for ascending aorta replacement, we removed the cannulas restricting the surgical area out of the site and successfully used the upper end mini-sternotomy incision. The innovative and "inventive" nature of our occupation makes being creative inevitable. Finding ways for applying successful and safe surgical intervention methods by using less invasive techniques and applying them with courage establish the future of minimally invasive cardiac surgery.

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Degeneration of a bioprosthetic valve in mitral position after 21 years of implantation

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Summary

Abstruct: Structural bioprosthetic valve degeneration is the most prominent drawback of these valves. The durability of bioprosthetic valve is less with mitral than aortic ones. Herein we present a case who had undergone a bioprosthetic mitral valve replacement 21 years ago when he was 31 years old. Echocardiography showed 3 degree mitral regurgitation with gradient 23/12 mmgh, systolic pulmonary artery pressure (SPAP) 48mmgh, left atrium diameter was 8 cm and 3 degree tricuspid regurgitation. The bioprosthetic valve in mitral position was replaced with No.29 st Jude mechanical valve and Tricuspid valve Devege annuloplasty was performed. The postoperative period was uneventful.

Keywords: Bioprosthetic valve, mitral position, valve replacement.

Case

Herein we present a case who had undergone bioprosthetic mitral valve replacement 21 years ago when he was 31 years old. He came to our clinic complaining from shortness of breath on heavy exertion. Echocardiography demonstrated 1 to 2 degree mitral regurgitation with gradient 16/10 mmgh, systolic pulmonary artery pressure 40 – 45 mmgh, 2 degree tricuspid regurgitation and left atrium diameter was 7.5 cm. Cardiac catheteriztion was performed and minimal mitral regurgitaion with systoic pulmonary artery pressure 60 mmgh was observed. We followed up the patient medically for 6 months, then he came back to our clinic camplaining from shortness of breath on light effort. Echocardiography showed 3 degree mitral regurgitation with gradient 23/12 mmgh, SPAP 48mmgh, left atrium diameter was 8 cm and 3 degree tricuspid regurgitation. Surgery was performed via re-median sternotomy and under mild hypothermic cardiopulmonary bypass. The bioprosthetic valve in mitral position was replaced with No. 29 st. jude mechanical valve and tricuspid valve Devege annuloplasty was performed. Gross examination of the explanted xenograft showed some degenartive changes of the cusps and the tissue was fragile (Figure.1). Pathologic studies revealed dystrophic calsifications and degenerative changes in the bioprosthetic valve. The postoperative period was uneventful. He was discharged on

the fourth day postoperatively. We called the patient 15 days later for general control. He did not have any complaint. The echocardiographic studies revealed minimal mitral regurgitation and SPAP was 38 mmgh.

Discussion

Durability expectations for tissue valves range from 5 to 20 years. Durability can be extended by treatments that address calcification and designs that address mechanical wear. Tissue valves have become a practical option for elderly patients and for those who cannot tolerate the anticoagulation therapy required for mechanical valve recipients. Time-related dystrophic calsification is one of the major limitations to the durability of bioprosthetic valves. In the present patient, the prosthetic valve became hard and fragile as a result of calcification, and this resulted in degenerative destruction.

The destruction of an implanted bioprosthesis in the heart would most likely be due to dynamic mechanical stress as well as to an immunological response to the glutaraldehyde-treated bioprosthesis.[15] As mentioned above, bioprosthetic valves dysfunction occurs more rapidly in the mitral than in the aortic position.

In the present case, the patient's medical record showed that dysfunctioning of the bioprosthesis in the mitral position was found 21 years after implantation; this period of bioprosthesis durability is unusually long for the mitral position and in a patient of this age. Mitral tissue valves have demonstrated susceptibility to calcification and wear due to the high systolic pressure placed on the closed leaflets. Here such calsification was observed after 21 years.

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- **arrhythmia,**
- **cardiovascular surgery,**
- **vascular & endovascular surgery,**
- **vascular biology**