Case Report

Reoperation for a Patient 25 Years after a Starr-Edwards Ball Mitral Valve was Installed

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A 45-year-old female suffered from increasing dyspnea during exercise and edema of lower extremities from January 2000. She had undergone mitral valve replacement with Starr-Edwards ball prosthesis (model 6320) due to mitral valve regurgitation 25 years ago. The cardiac catheterization and echocardiography documented mitral, aortic and tricuspid valves regurgitation grade III. Left ventricular ejection fraction rate was 49% and the pressures of CVP, RA, RV and PA were also increased. Laboratory examination showed slight hemolytic anemia. Double valve replacement (ATS valve) and tricuspid annuloplasty were carried out in April 2000. Strut cloth wear was confirmed at operation. Her postoperative course was uneventful. We hereby review the published paper of all cases with an implanted Starr-Edwards ball valve who required redo valve replacement with over 15 years follow-up. We consider that cloth injury is the main cause for reoperation and it usually associated with hemolytic anemia; cloth wear not only involves the aortic position but also frequently involves the mitral position for over 15 years follow-up patients and can be corrected by reoperation. Cloth wear should be concerned for those surviving patients who have received the Starr-Edwards ball valve during long-term follow-up. (Ann Thorac Cardiovasc Surg 2002; 8: 311–5)

Key words: Starr-Edwards ball valve, reoperation, cloth wear, valve replacement

Introduction

It is well known that surgical treatment using a mechanical valve is as one of the commonest treatments for valvular diseases. The first successful prosthetic replacement for aortic and mitral valves was reported by Harken and associates[1] and Starr and associates[2] 41 years ago. These historic surgical procedures mark the beginning of the modern era of heart valve replacement. The Starr-Edwards ball prosthetic valve was the first of many to be used commercially in clinics. Implantations of Starr-Edwards valves, which experienced several modifications, exceed 200,000 cases and long-term results with this valve have recently been reported showing satisfactory results with reliable durability and safety, and could represent the gold standard in mechanical valve replacement.[3]

However, reoperation after valve replacement with Starr-Edwards ball valve is unavoidable. In the present paper we report a case whom required re-replacement for Starr-Edwards ball valve 25 years after implantation. We herein review the development, valve-related complications and reoperation for Starr-Edwards ball prostheses.

Case Report

A 45-year-old female underwent mitral valve replacement with Starr-Edwards ball cage prosthesis (model 6320) in April of 1974 due to mitral valve regurgitation with endocarditis. She was given warfarin and ticlopidine (200 mg/day) for anticoagulation with thrombo test level controlled at 10-20% and/or international normalized ratio (INR) at 1.8-2.0. Valve dysfunction after valve replacement had never occurred until January 2000 when she suffered from increasing dyspnea during exercise and

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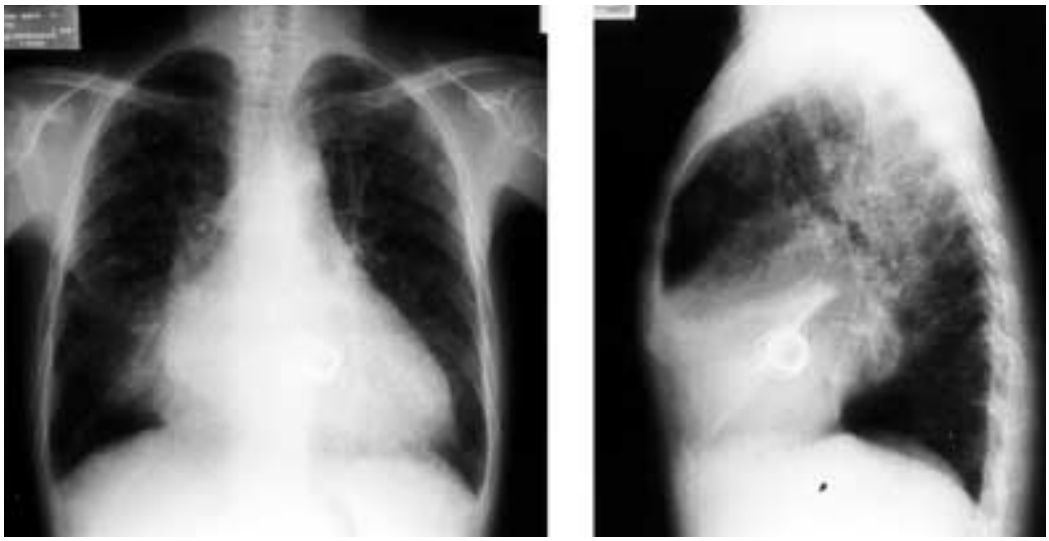

Fig. 1. Preoperative Chest X-ray film.

edema of lower extremities, and she was diagnosed with heart failure.

Chest X-ray film showed severe cardiomegaly (CTR 68%) and pulmonary congestion (Fig. 1). The cardiac catheterization documented mitral, aortic and tricuspid valve regurgitation grade III according to Sellers classification, it demonstrated pulmonary artery pressure of 68/30 mmHg (mean 48 mmHg), pulmonary capillary wedge pressure of 38/25 mmHg (mean 35 mmHg), and central venous pressure of 16 mmHg. Left ventricular ejection fraction was 49%. Cinefluoroscopy showed good ball movement.

Echocardiogram showed that the peak pressure gradient of the mitral valve was 25 mmHg, pressure half time was 340 msec, and mitral, aortic and tricuspid regurgitation grade III. However valve dysfunction such as cloth wear was not recognized. Laboratory data showed middle grade hemolytic anemia with hemoglobin of 10.2 g/dl, hematocrit of 29.2%, and serum lactate dehydrogenase (LDH) of 360 U/l.

Due to this diagnosis, double valve replacement and tricuspid annuloplasty were carried out in April 2000. Under general anesthesia, cardiopulmonary bypass (CPB) was started with cannulation of the right femoral artery (FA), superior vena cava (SVC) and inferior vena cava (IVC). After the right atrium and atrial septum were opened, we examined the previous implanted ball valve. The cloth of the cloth-covered strut had partial tears and the strut was exposed (Fig. 2). After the ball valve was excised, we replaced it with on ATS valve (27 mm) in a para-annular position, then the aortic valve was replaced with an ATS valve (20 mm AP) in a supra-annular position. After declamping of aorta, we performed tricuspid annuloplasty with a Cosgrove-Edwards annuloplasty ring (30 mm). Weaning from CPB was uneventful. No problems were found in both artificial valve positions and post-annuloplasty tricuspid valve position on postoperative echocardiography and the left ventricular ejection fraction increased to 65%. The postoperative course was uneventful, the patient was discharged 20 days after operation. Postoperatively, the patient was given warfarin and ticlopidine (200 mg/day) for anticoagulation with thrombo test level controlled at 10-20% and/or international normalized ratio of prothrombin time (PT-INR) at 1.8-2.0.

Discussion

The Starr-Edwards ball valve was the first artificial valve introduced to the world in 1961 by Professor Albert Starr.[2] This was a revolutionary event in cardiac surgery at that time. Since the introduction of the original Starr-Edwards ball valve, there have been several revisions to improve the hemodynamic characteristics and decrease the incidence of thromboembolism. There were three models of prostheses introduced during that period: a non-cloth-covered model has been in continuous use since 1965; a

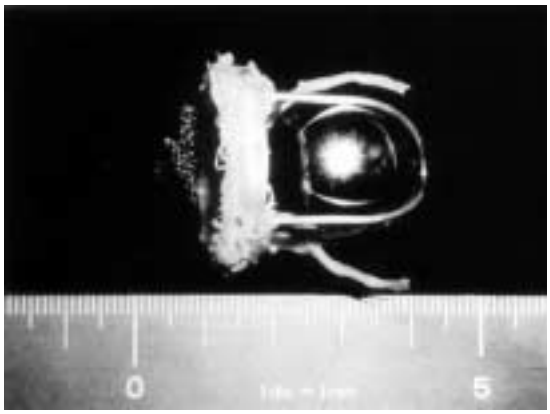

Fig. 2. Excised Starr-Edwards ball valve (model 6320).

cloth-covered model was begun in 1968 and has been supplanted by the modified composite-strut or "track" model since 1972.[4] The first generation of ball-valve prostheses, models 6000 and 6120 (mitral) and 1000 and 1200/60 (aortic), were without any cloth covering and had bare metallic struts composed of Stellite, but thromboembolism was a major problem with postoperative anticoagulant therapy, furthermore, poppet damage owing to fatty infiltration of the silicone rubber ball, a phenomenon termed ball variance also occurred at that time. To solve these problems, totally cloth-covered valvular protheses (model 6300/20 mitral and 2300/20 aortic) were introduced. Covering the metallic struts with cloth reduced the incidence of thromboembolism, but lead to problems with cloth wear, the Starr-Edwards model 6400 mitral and 2400 aortic, introduced in 1975, have metallic tracks on the inner aspect of cloth-covered struts to eliminate cloth wear while retaining improved throboembolic performance and results appear promising.[5,6]

Complications of Starr-Edwards ball valve occurring with variable frequency are thromboembolism, thrombosis, anticoagulant-related hemorrhage, paravalvular leakage, and/or endocarditis, which are the main limitations of any mechanical prosthesis, while thrombotic complication is predominant in the first generation of the Starr-Edwards ball valve. Rare complications are ball variance which usually occurs in early postoperative years, most of the cases were discovered before 8 years, but some late severe ball variance can exist up to 20 years after implantation[7]; pannus formation or excessive tissue ingrowth; cloth wear or cloth tears; strut failure; and dislodgement of ball which is really a rare but lethal complication.[8] These rare complications can be regarded as unique problems of the Starr-Edwards ball valve.

In order to solve the main problem of thrombotic complication in the first generation of the Starr-Edwards ball valve, the cloth-covered model was developed, and it significantly decreased the incidence of thromboembolism than the older model, but the problem of cloth wear or tears unexpectedly occurred.

The incidence of cloth wear within 10 years follow-up in surviving patients who had a cloth-covered Starr-Edwards ball valve replacement is less than 2.6%,[9-11] with a 12 to 15 years follow-up is 6%,[12] while true incidence of cloth wear over 15 years follow-up is not definitely reported.

Though rare, the possibility of cloth injury was subjected to a higher risk of reoperation. In the early stage of valve replacement by a cloth-covered Starr-Edwards ball valve, cloth wear was the main cause for those requiring reoperation. In a report by Starr,[11] among 250 patients with model 2310/20 prosthesis, there were 14 patients who needed reoperation and 10 (71%) patients were found to have strut cloth wear at operation; among 171 patients with model 6310/20 prosthesis, there were 9 patients who needed reoperation and 2 patients were confirmed to have orifice cloth tear. Our group[13] previously has also reviewed the reoperation cases for Starr-Edwards ball valve, there were 12 patients who required reoperation in our institution, 9 (75%) of them were confirmed to have cloth wear at reoperation. In that study, the mean interval at reoperation for a Starr-Edwards ball valve was 7.9 years at that time, marked cloth wear was observed in all aortic prostheses, but only slight wear in mitral valves. Nowadays, most of the still surviving patients who received a valve replacement with a Starr-Edwards ball valve have survived at least 15 years after the operation. Some of them needed reoperation mainly for valve-related complications or aggravated other valve lesions during the follow-up period. So in the present paper we also review the detail data of the related reports for more than 15 years after initial operation (Table 1).[14-21] Table 1 summarizes all 11 cases (including the reported case) who needed reoperation due to Starr-Edwards ball valve related complications over 15 years follow-up, the mean valve age at operation is 20.1 years (range from 15 to 29); of these cases, 8 are in the mitral position, and 3 in the aortic position. At operation, 8 were found to have obvious cloth wear, one was cloth tear of the valve seat, the other 2 patients were thrombosed valve and pannus formation. Among the 8 cloth injury cases, 5 are in the mitral posi-

Table 1. Reported reoperative cases for those who have had a Starr-Edwards ball valve installed for more than 15 years in the literature

Author (year)	Position	Valve model	Valve age	Laboratory finding	Finding at operation	Surgical procedure
Fukushima[14] (1988)	Mitral	6300	18 year	HA	Pannus	Re-MVR
Akiyama[15] (1990)	Mitral	NS	16 year	HA	CW	Re-MVR+TAP
Ozaki[16] (1992)	Mitral	6300	16 year	–	Thrombosed valve	Re-MVR
Aoyagi[17] (1992)	Mitral Aortic	NS NS	15 year 20 year	HA HA	CW CW	Re-MVR+AVR+TAP Re-AVR+MVR+TAP
Tabayashi[18] (1994)	Aortic	2320	19 year	HA	CW	Re-AVR
Ko[19] (1995)	Mitral	6320	22 year	HA	CW, PVE, Pannus	Re-MVR+TVR
Sakata[20] (1997)	Mitral Mitral	6320 6320	21 year 21 year	HA –	CW, Panuus CT of vavle seat	Re-MVR+TAP Re-MVR
Sugawara[21] (2000)	Aortic	2320	29 year	HA	CW, Panuus	Re-AVR+MVR
Our case (2002)	Mitral	6320	25 year	HA	CW	Re-MVR+AVR+TAP

NS: not stated, HA: hemolytic anemia, CW: cloth wear, PVE: paravalvular endocarditis, CT: cloth tear, MVR: mitral valve replacement, AVR: aortic valve replacement, TAP: tricuspid valve anuuloplasty

tion, 3 are in the aortic position and all of the 8 cloth injury cases are associated with hemolytic anemia. Unlike the previous reports for those early or mid-term follow-up,[9,11,13] the cloth wear frequently involves the mitral position for those over 15 years follow-up.

Cloth disruption may be associated with hemolytic anemia, embolic consequences, or both, while some of them may be asympotamic. The diagnosis of cloth injury is difficult and it is almost impossible before reoperation for cloth wear, but cloth tears can be detected by echocardiography.[10]

In the reported case, the patient had been living well for 25 years without any valve related complications, and her Starr-Edwards ball valve demonstrated a good long-term durability and reliability. Moreover, with increasing complicated procedures and risk factors, reoperation for those with previously installed Starr-Edwards ball valve dysfunction necessitating replacement is available with good surgical results to achieve a better survival rate. Although our case did not show cloth wear by echocardiography and her hemolytic anemia was not severe, cloth wear was recognized at reoperation. Furthermore, we choose an ATS valve as the prosthetic valve at reoperation for the present case, the ATS valve is excellent for prevention of hemolysis and thromboembolism, and it shows good valve function and offers a superior quality of life. The ATS valve is the first choice for a mechanical valve from 1993 in our institute.[22-24]

We can draw a conclusion as follows: cloth injury is the main cause for reoperation and it usually associated with hemolytic anemia; cloth wear not only involves the aortic position but also frequently involves the mitral position for over 15 years follow-up and can be corrected by reoperation. So early diagnosis and treatment of this valve-related complication are important to improve the long-term results for surviving patients who received the Starr-Edwards ball valve.

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