Original Article

Prophylactic Reoperation after Mitral Valve Replacement with the Starr-Edwards Ball Valve: A Report of Four Cases

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Purpose: The Starr-Edwards ball valve was first applied clinically in 1960. In our hospital, this valve has been used since 1963, and some patients have been followed up for 30 years or more. Based on our experience, therapeutic strategies included revalve replacement as a preventive procedure in the absence of valve-related complications. In this study, we investigated whether prophylactic reoperation after valve replacement with the Starr-Edwards ball valve is appropriate.

Patients and Methods: Of 58 patients in our institute who underwent mitral valve replacement with the Starr-Edwards ball valve, 12 underwent revalve replacement. Of these 12, the subjects of the present study were 4 patients who underwent prophylactic revalve replacement.

Results: The mean postoperative follow-up of the 4 patients was 31.0±3.7 years. There were no operative deaths or postoperative complications. On examination of the extirpated Starr-Edwards valves, cloth wear was observed in all 4 patients. Although there was no influence on the range of ball motion, they showed the entity of "thrombus/pannus."

Conclusion: In this study, all of the patients showed cloth wear in the absence of complications. Therefore we consider that prophylactic reoperation after valve replacement with the Starr-Edwards valve should be performed to prevent complications. (Ann Thorac Cardiovasc Surg 2007; 13: 316–321)

Key words: valve replacement, reoperation, mechanical valve, valve disease, heart valve

Introduction

The Starr-Edwards valve was first used in the clinical field in 1960,[1)] and it markedly improved the results of surgery for valvular diseases. Thereafter a tilting disc valve replaced the mechanical valve, and currently a bileaflet valve is mainly used. Although the Starr-Edwards ball valve is durable, it provides unfavorable hemodynamics compared with the bileaflet valve, in which central flow is obtained, with a high incidence of valve-related complications, such as thromboembolism and hemolytic anemia. Previously, we reported on 12 patients who underwent reoperation with the Starr-Edwards valve, including patients after an aortic valve replacement. In these patients, reoperation was performed because of complications, such as thromboembolism and prosthetic valve endocarditis, or valve dysfunction. On examination of the extirpated valves, cloth wear or pannus was observed in all 12 patients.[2)] Therefore since 2000, our hospital has performed reoperation with informed consent as a prophylactic procedure, even in patients without heart fail-

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Received September 27, 2006; accepted for publication June 12, 2007

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Table 1. Patient background

Case	Age	Gender	Model	Interval until reoperation (years)	Procedure at reoperation
1	45	Female	3M 6320	25.9	MVR, AVR, TAP
2	61	Female	3M 6320	31.4	MVR, TAP
3	57	Female	3M 6320	32.0	MVR, TAP
4	66	Female	3M 6320	34.7	MVR, TVR

MVR, mitral valve replacement; AVR, aortic valve replacement; TAP, tricuspid annuloplasty; TVR, tricuspid valve replacement.

Table 2. Patient status before and after surgery

	LDH (U/L)		CTR (%)		EF (%)		LAD (mm)		Noise index*	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	705	251	68	53	60	73	70	48	6	0
2	434	410	75	55	51	56	75	63	6	0
3	339	202	60	51	62	68	56	51	5	0
4	473	266	70	63	50	56	50	48	5	1
Average	415.3±68.9	299.3±104.6	68.3±7.6	56.3±6.1	54.3±6.7	60.0±6.9	60.3±13.1	54.0±7.9	5.3±0.6	0.3±0.6

LDH, lactate dehydrogenase; CTR, cardiothoracic ratio; EF, ejection fraction; LAD, left atrium diameter.

ure symptoms or those who did not require reoperation because of mild heart failure symptoms. In this study, we investigated whether prophylactic revalve replacement is appropriate in 4 patients who underwent this procedure in our hospital.

Patients and Methods

Of 58 patients who underwent mitral valve replacement with the Starr-Edwards ball valve in our hospital from 1963 to 1977, the follow-up rate was 84.5% and the mean number of follow-up years was 17.0 (0–36.9). The revalve replacement was performed in 12 patients. Eight required revalve replacement because of prosthetic valve-related complications. In the Starr-Edwards ball valves extirpated from the 8 patients, cloth wear or pannus was observed. The subjects of the present study are 4 patients who underwent prophylactic revalve replacement. Prior to surgery, informed consent regarding the need for prophylactic revalve replacement and the risk of reoperation was obtained from all 4. The indication criteria included (1) an interval of 20 years or more after valve replacement, (2) a cardiothoracic ratio (CTR) of 60% or more on chest X-ray, (3) patients of less than 70 years of age, (4) an ejection fraction (EF) of 50% or more on an echocardiogram, (5) a left atrial diameter of 50 mm or more on a transesophageal echocardiogram, and (6) the presence of left atrial smoke-like echoes on a transesophageal echocardiogram. Our subjects were cases that did not require reoperation, either because there were no heart failure symptoms or because mild heart failure symptoms could be controlled by drug therapy.

The mean age at reoperation was 57.3±9.0 years (45–66). All of the subjects were women, and the previous procedure had been mitral valve replacement (model 6320), with a mean postoperative follow-up of 31.0±3.7 years (25.9–34.7) (Table 1). On chest X-rays, the mean CTR was 68.3±7.6% (60–75%), and the mean left ventricular EF on transthoracic echocardiogram was 54.3±6.7% (50–62%). The left atrial diameter was 60.3±13.1 mm (50.0–75.0 mm). In all 4 patients, smoke-like echoes were observed in the left atrium. The serum lactate dehydrogenase (LDH) level was 415.3±68.9 U/L (339–705 U/L) (Table 2). On preoperative cinefluoroscopy, none of the patients showed any abnormalities in ball motion.

Results

All patients underwent remitral valve replacement with the ATS valve (ATS Medical Inc., Minneapolis, USA). Three simultaneously received tricuspid annuloplasty; 1 received tricuspid valve replacement, and another received aortic valve replacement. All 4 patients showed atrial fi-

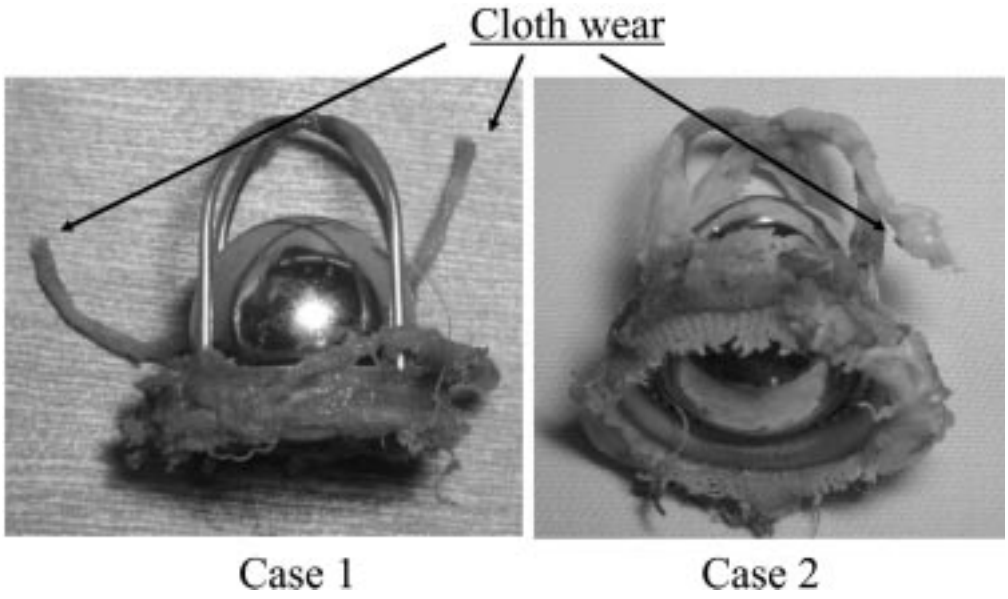

Fig. 1. Starr-Edwards valves extirpated from patients 1 and 2.

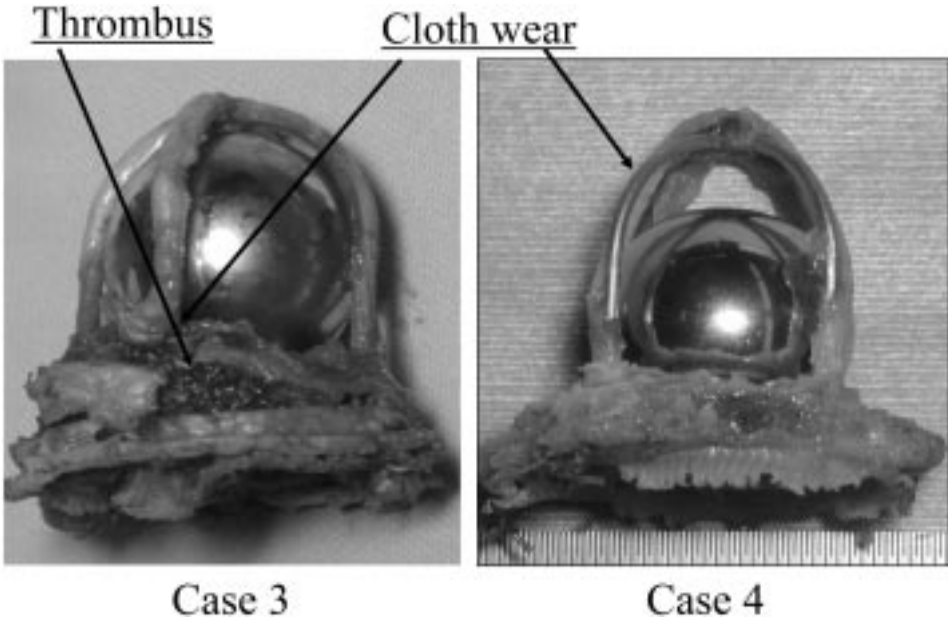

Fig. 2. Starr-Edwards valves extirpated from patients 3 and 4.

brillation preoperatively; a left atrial plication was performed, but the Maze procedure was not.

There was no operative death or postoperative complication, and all patients could be discharged [mean duration of postoperative hospitalization: 16.3±4.0 days (14–21 days)]. On transthoracic echocardiography at 6 months after surgery, the mean EF was 60.0±6.9% (56–73%), significantly higher than the preoperative value. The mean CTR, left atrial diameter, and serum LDH level were 56.3±6.1% (51–63%), 54.0±7.9 mm (48–63 mm), and 299.3±104.6 U/L (202–410 U/L), respectively, showing that significant improvement was achieved (Table 2). All patients noticed that the valve sound was quiet compared with a ball valve. Three of the 4 patients said they did not

notice prosthetic valve sounds. The mean noise index,[3] which we proposed to score stress related to prosthetic valve sounds, was 5.3±0.6 points (5–6 points) before surgery, and after reoperation the value was significantly decreased, to 0.33±0.58 point (0–1 point), suggesting relief of stress related to prosthetic valve sounds (Table 2). After surgery, all of the patients were satisfied with the reoperation and recognized the improvement of stress related to prosthetic valve sounds. Therefore an improvement in the quality of life (QOL) was achieved.

When we examined the extirpated Starr-Edwards prosthetic valves, cloth wear was observed in all 4 patients. In 2 patients, all four cages showed cloth wear, and in another 2 three cages showed cloth wear. Furthermore, cloth wear involvement per cage was 50% or more in 2 patients. In patient 1, the cloth of two cages had completely disappeared. In another patient, a thrombus was adhered to the sewing cuff. All patients showed pannus; however, there was no overgrowth, and there was no influence on ball motion (Figs. 1 and 2).

Discussion

Since its appearance in 1960, the Starr-Edwards valve has markedly improved the results of surgery for valvular diseases. The initial-type Starr-Edwards valve consisted of stainless cages and a silicon ball, but it was improved to a new type. The valve has a hollow Stellite alloy ball, and its cages are covered with a Teflon fiber cloth, aimed at avoiding frequent thromboembolism or ball variance. Moreover, the inside of the cages has been further improved with a Teflon fiber-free material, because the wear of Teflon fibers in the cages related to friction with the ball (cloth wear) caused hemolysis or embolism.[1,4] Gao et al. reported long-term results of this valve over 40 years in a hospital to which Dr. Starr had belonged. According to their study, the 10-, 20-, and 30-year cumulative survival rates for the mitral position were 51, 23, and 8%, respectively.[6] Gödje et al. reported 20- and 30-year actuarial survival rates of 36.5 and 22.6%, respectively.[7] In our hospital, the 20-, 30-, and 35-year actuarial survival rates for the mitral position were 61, 33, and 25%, respectively (Fig. 3); the percentages were higher than those in the above two hospitals. The reason for this is unclear; however, this was possibly because our patients were younger (32.8±11.1 years) compared with patients in the above two hospitals (the study described by Gao et al.: 55.5±13.0 years; the study described by Gödje et al.: 40.1±10.1 years [including patients who underwent aortic valve replacement]).

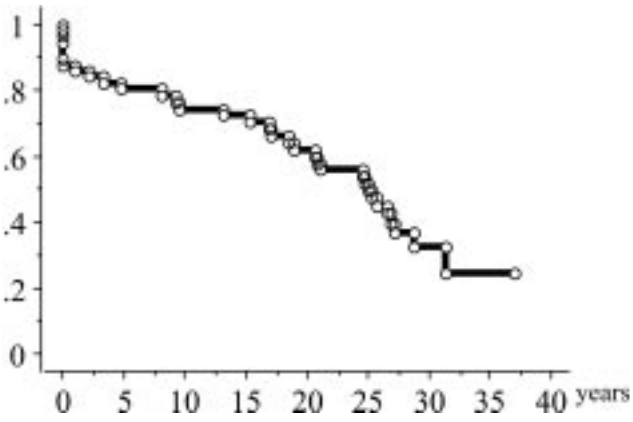

Fig. 3. Actuarial survival curve for the Starr-Edwards valve in the mitral position in our hospital.

It has been reported that the incidence of complications using the Starr-Edwards valve, such as thromboembolism, is higher compared with complications from the bileaflet valve. An etiological factor is cloth wear. The incidence of cloth wear is reported to be 0.4–2.6%/patient-year, based on the results of the autopsy/examination of reoperation.[8–10] Shah et al. have indicated that the following findings suggest cloth wear: (1) transient cerebral ischemia attacks, or infarctions of systemic organs, that recur despite appropriate anticoagulant therapy; (2) arterial embolism that develops more than 4 years after valve replacement with a cloth-covered valve; (3) increased metal clicking sounds; (4) persistent severe hemolytic anemia; and (5) abnormalities in the positional relationship between the ball and the valve location at the valve opening/closure under fluoroscopy, or a regurgitation of contrast medium from the valve orifice.[10] Shapira et al., investigating how cloth wear can be detected by transthoracic echocardiography, reported that floating thin, long echoes adhering to the cages were observed in 6 (17.1%) of 35 patients in a follow-up period of 20 years or more after valve replacement with the Starr-Edwards valve, and that no symptoms occurred in 2 of these patients.[11] According to a case report, Geiser performed transthoracic echocardiography in a patient who underwent mitral valve replacement, and the findings suggested cloth wear. Therefore reoperation was performed, and cloth wear was observed, as demonstrated by transthoracic echocardiogram findings. He expressed the findings as "rabbit ears."[12] Moreover, recent advances in transesophageal echocardiography have facilitated the detection of cloth wear. Vermes et al. performed

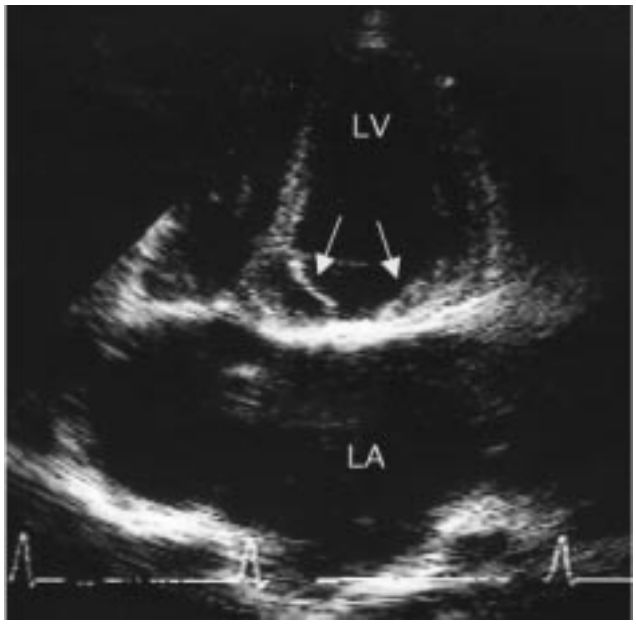

Fig. 4. Preoperative transthoracic echocardiogram in patient 1. LV, left ventricle; LA, left atrium. Arrows: cloth wear.

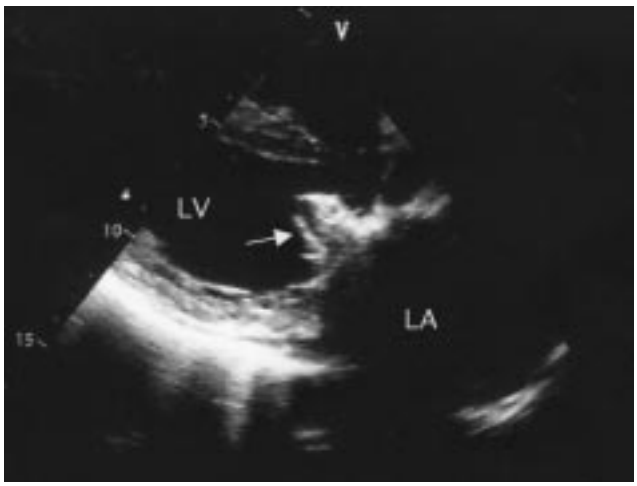

Fig. 5. Preoperative transthoracic echocardiogram patient 4. LV, left ventricle; LA, left atrium. Arrow: cloth wear.

transesophageal echocardiography in 9 patients in whom no symptoms occurred after aortic valve replacement. The findings suggested cloth wear in 5 patients, and reoperation was performed on 1. They reported the cloth wear to be more extensive compared with observation by transesophageal echocardiography, and the transthoracic echocardiography findings did not suggest cloth wear in 5 of the 9 patients.[13] The 4 patients investigated in the present study showed none of the five parameters of cloth wear proposed by Shah et al. Transthoracic echocardiography was performed on all of the patients, and transesophageal echocardiography was performed on 4. We did not investigate the presence or absences of cloth wear on the preoperative echocardiogram. Therefore we checked all examinations on stored videotape and reviewed whether the findings suggested cloth wear. In 3 patients, transthoracic echocardiogram showed floating thin, long echoes adhering to the cages, suggesting cloth wear. In particular, in patient 1 the extirpated valve revealed a complete exfoliation of cloth, which was consistent with the transthoracic echocardiogram findings. In patient 4, the findings were also similar between the extirpated valve and transthoracic echocardiography (Figs. 4 and 5). In 1 patient whose findings did not suggest cloth wear, the extirpated valve revealed mild cloth wear; visualization by transthoracic echocardiogram was considered difficult in this patient. A transesophageal echocardiogram suggested no cloth wear, possibly because ball/cage artifacts made the detection of cloth wear difficult in the present patients who underwent mitral valve replacement. Transthoracic echocardiography in patients after Starr-Edwards valve replacement in the mitral position, and transesophageal echocardiography in such patients after this procedure in the aortic position, may be useful for evaluating the need for reoperation.

Many patients required reoperation because a cloth-wear–related hemolytic anemia/thromboembolism had been reported. However, there are no case reports on prophylactic revalve replacement as reported in this study. Previously, we reported on 12 patients who underwent reoperation with the Starr-Edwards valve, including patients who underwent an aortic valve replacement. These patients underwent reoperation because of complications, such as thromboembolism and prosthetic valve endocarditis, or valve dysfunction. Examination of the extirpated valves showed cloth wear or pannus in these patients.[2] Therefore, since 2000, reoperation as a prophylactic procedure has been performed in our hospital for patients that had surgery 20 or more years ago. This includes even patients without heart failure symptoms or who required no reoperation as a result of mild heart failure symptoms, based on informed consent, when they have our indication criteria, described in Patients and Methods. We have performed prophylactic revalve replacement in 4 patients,

and the valves extirpated from those patients showed cloth wear; prophylactic reoperation with the ATS valve was considered appropriate. It is only 10 years since the clinical application of the ATS valves started, and reports of long-term results are expected. Because of the lower incidence of prosthetic valve-related complications and lower noise, the ATS valve is considered the first choice as the most reliable and consistently used mechanical valve.[3,14] In the patients with no history of thromboembolism, the LDH level was slightly increased, to 400 IU/L or more, but hemolytic anemia did not occur, and generally reoperation was not required.

This study suggests that close follow-up (transthoracic echocardiography in the mitral position, transesophageal echocardiography in the aortic position, prosthetic valve sound, and so on) should be continued in patients after Starr-Edwards valve replacement, considering the development of complications, so that the timing of reoperation is not missed even in the absence of complications. In particular, prophylactic reoperation may be useful for improving QOL in patients less than 70 years old in whom cardiac function is maintained when informed consent regarding the contents and risks of reoperation are obtained. Furthermore, as an examination prior to reoperation, transthoracic echocardiography was considered more useful than transesophageal echocardiography in patients who underwent valve replacement in the mitral position in this study. Therefore we would like to add the following criterion to the above indication criteria for prophylactic reoperation after valve replacement with the Starr-Edwards valve replacement, which we proposed: (7) the presence of cloth wear suggested by transthoracic/transesophageal echocardiography. The subjects of this study, as well as all subjects who had surgery 20 or more years ago and who underwent reoperation in our institute, showed cloth wear. We believe that patients who had surgery 20 or more years ago need reoperation regardless of whether they show symptoms of heart failure to prevent complications related to prosthetic valves. However, at this stage we consider that reoperation should not be performed on patients who are at high risk because of advanced age and/or severe cardiac dysfunction, and also not on patients in which adequate consent cannot be obtained. The number of cases of prophylactic reoperation may increase in the future as more attempts are made and the risk of reoperation lowers.

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