The Long-term Follow up Results of Kay-Shiley Heart Valve Prostheses

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Summary

Three hundred and thirty six Kay-Shiley disc valves were implanted in 323 cases from 1968 to 1975 at the Hacettepe University Hospital, Ankara. Eight patients died during surgery. Of the 328 valve replacements followed postoperatively, 263 were in the mitral (80.2%), 26 in the aortic (8%) and 39 in the tricuspid position (11.9%). Three hundred and fifteen patients were evaluated in the early and late postoperative periods. In the early period 52 patients died (16.5%). The remaining cases were followed up for 1–16 years (3381 patient-years). Twenty eight patients remain alive at the time of this report (10.6%). The longest survivors are 2 of the mitral valve replacement cases. The actuarial survival estimates were 88±2.4% at 1 year, 60.3±3.4% at 5 years, 36.3±3.9% at 10 years for all cases. The incidence of thromboemboli was 4.2% per patient-year in the late period in both the overall and the isolated MVR groups. Valve failure due to thromboses was detected in 8 patients (3%). Six patients were reoperated on in the late period (2.3%).

Additional Indexing Words:

Kay-Shiley Caged-disc heart valve prostheses Artificial valves

KAY-SHILEY heart valve prostheses were welcomed with great enthusiasm throughout the world for a period of time beginning in 1965, when some disadvantages of caged-ball prostheses were observed, and efforts to improve the valve design were focused on low profile caged-disc valves. This concept had affected our valve policy for a while and Kay-Shiley (K-S) prostheses had become the first choice artificial valve in our clinic for 3 years from 1969 to 1971.

The purpose of this article is to review the early and late results of Kay-Shiley implanted cases 20 years after the first replacement and to

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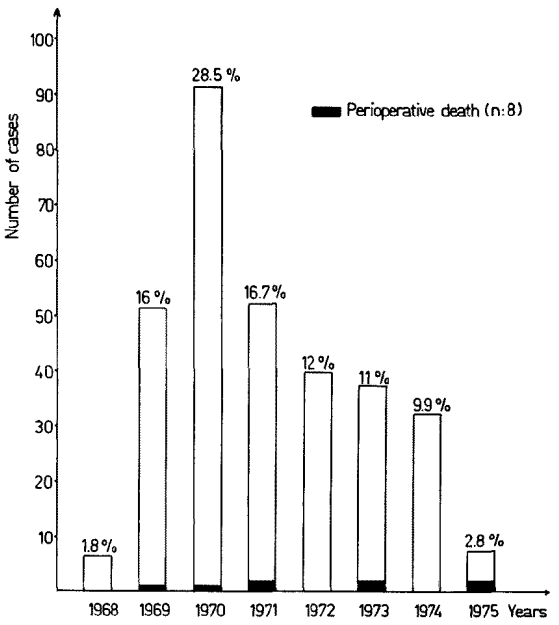

Fig. 1. Yearly distribution of 323 cases.

present the factors leading to use of this prosthesis being discontinued.

Materials and Methods

Between 1968 and 1975, 336 K-S disc valves were implanted in 323 patients in our hospital. The youngest patient was 2 and the oldest one was 61 years old; the male-female ratio was almost 1:1 (49.5%/50.5%). The average age was 29.3 years. Yearly distribution of the cases is depicted in Fig. 1 and the classification by sex and age groups is shown in Fig. 2.

According to the NYHA functional classification, the majority of the cases were in class III (54.7%) or class II (37.7%). Preoperative cardiac rhythm was sinus in 24% and atrial fibrillation in the remaining cases (76%).

Eight patients died during surgery (2.4%). One hundred and eighty nine of the operative survivors were single valve replacements (60%) (Table I). Concomitant valvuloplasty as well as single valve replacement was performed in another 28 patients (8.9%). The remaining 98 cases were multiple valve replacements (31%).

Briefly, of the 328 valve implantations followed postoperatively, 263 were in the mitral (80.2%), 26 in the aortic (8%) and 39 in the tricuspid position (11.9%) (Fig. 3).

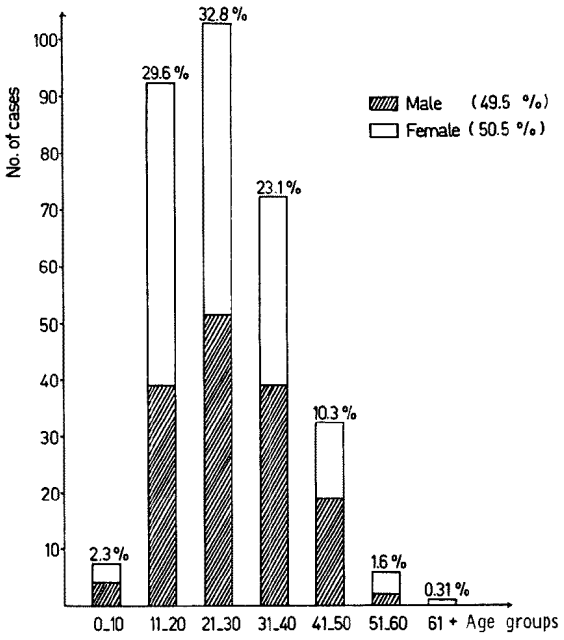

Fig. 2. Sex and age distribution (n: 323).

During surgery, left atrial thrombus was detected in 6 cases (1.9%) and mitral valve calcification in 35 cases (11.1%).

Mitral and tricuspid prostheses were implanted with 2–0 Ti-Cron interrupted sutures in 32 patients (10.6%) and with a continuous suture technique in the remaining 270 patients (89.4%). Interrupted 2–0 Ti-Cron figure eight sutures were used in all of the aortic valve replacements. Postoperatively, all patients were anticoagulated with warfarin sodium and since 1971 antiaggregant drugs such as diprydamole and acetylsalysylic acid have been added to the therapy.

Four of the mitral valves were implanted without aortic cross clamping in 1968 and 1969. However, anoxic cardiac arrest has been used in all patients since them. Aortic cross clamping time ranged from 15 to 55 min for mitral valve replacements (mean 27 min), 40–140 min for aortic (mean 58 min) and 42–151 min (mean 98 min) for multiple valve replacements.

The outcomes of 315 operative survivors have been evaluated in early and late follow up periods. Results were obtained from the patients' files or folders and the patients about whom we did not have enough information were sent letters and asked to get in touch with us. Those who were not able to come were asked to answer a questionnaire.

Table I. Surgical Interventions Performed in 315 Cases in Whom 328 Kay-Shiley Prostheses Were Implanted

Surgical intervention	Number of cases	
Isolated valve replacement	189	60.0%
AVR	3	1.0%
MVR	186	59.0%
Replacement with K-S+valvuloplasty	28	8.9%
AVR (K-S)+mitral commissurotomy	1	0.3%
MVR (K-S)+tricuspid annuloplasty	22	7.0%
MVR (K-S)+removal of subaortic stenosis	1	0.3%
TVR (K-S)+mitral commissurotomy	4	1.2%
Multiple valve replacement with K-S	13	4.1%
MVR TVR	12	3.8%
MVR AVR TVR	1	0.3%
Multiple replacement with various prostheses (K-S+another type of prosthesis)	85	26.9%
K-S in mitral position	41	13.0%
K-S in aortic position	22	7.0%
K-S in tricuspid position	22	7.0%

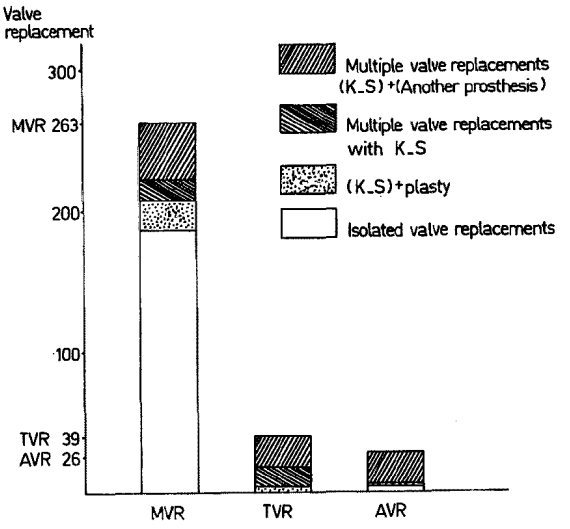

Fig. 3. The distribution of 328 valve replacements according to the valve position (n: 315).

Results

In the early follow up period covering the first 30 postoperative days, 52 cases died (Table II). The most common cause of mortality in this period was ventricular fibrillation, followed by left ventricular failure and cerebral emboli (5.1, 4.1 and 4.1%, respectively).

Late outcome of the 263 surviving cases was investigated for long-term results. We were unable to get enough information about 112 patients (42.6% lost to follow up). Fifty seven patients answered the questionnaire (21.7%). Follow up results of 77 cases were obtained from hospital files (29.2%); 17 patients were examined in the hospital (6.4%). There were only 28 patients still surviving (10.6%) and the longest survivors were 2 of the mitral cases (16 years).

When the statistical study was done, we realized that the main problem was related to those patients lost to follow up where we could not determine if they still survived. To minimize the statistical errors, we prepared a life-table, which was compiled by standard methods.[1] Standard errors were

Table II. The Causes of Mortality in the Early Follow-up Period (n: 315)

	Cause of death	Number of deaths	Incidence in each group
Isolated valve replacement	Ventricular fibrillation	8(38%)	11.1% of 189 cases (21 deaths)
	Cerebral embolism	5(23.8%)	
	Left ventricular failure	5(23.8%)	
	G.I. bleeding	1 (4.8%)	
	Infective endocarditis	1 (4.8%)	
	Myocardial infarction	1 (4.8%)	
Replacement with K-S+ valvuloplasty	Cerebral embolism	3	10.7% of 28 cases
Multiple valve Replacement with K-S	Ventricular fibrillation	1(33.3%)	23.1% of 13 cases (3 deaths)
	Left ventricular failure	1(33.3%)	
	Cerebral embolism	1(33.3%)	
Multiple replacement with various prostheses (K-S+another type of prosthesis)	Ventricular fibrillation	7(28%)	29.4% of 85 (25 deaths)
	Left ventricular failure	7(28%)	
	Cerebral embolism	4(16%)	
	Myocardial infarction	2 (8%)	
	Infective endocarditis	2 (8%)	
	Right ventricular failure	1 (4%)	
	Renal failure	2 (8%)	
Total		52 deaths (16.5% of 315 cases)	

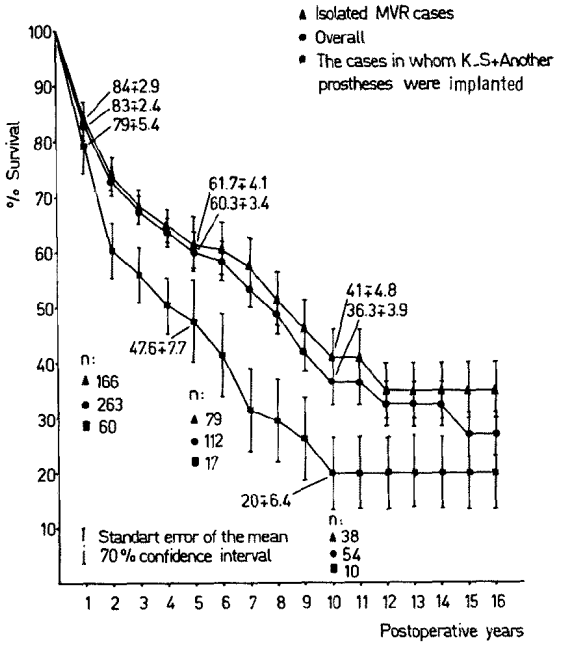

Fig. 4. The actuarial survival rates.

Table III. The Causes of Mortality in the Late Postoperative Period (n: 263)

Causes of late deaths	
Cerebral embolism	16(13%)
Left ventricular failure	22(17.9%)
Prosthetic valve endocarditis	6 (4.9%)
Sudden death	46(37.4%)
Unknown cause	33(26.8%)
Total	123 (3.6% per patient-year)

calculated according to the Greenwood formula.

Two hundred and sixty three cases surviving the early period were followed for approximately 1–16 years (mean 12.8 years). Total follow up is 3381 patient-years. The long-term actuarial survival curve of all cases (n: 263) is illustrated in Fig. 4. The actuarial survival estimates are 88± 2.4% at 1 year, 60.3±3.4% at 5 years and 36.3±3.9% at 10 years. In this illustration only 3 groups of cases are depicted since the other groups comprise insignificant numbers of patients.

Isolated MVR cases were followed for an average of 13.1 years (2166 patient-years). The survival rates for this group are very close to those of

the overall group (84±2.9, 61.7±4.1 and 41±4.8%, respectively).

Sixty cases in whom both K-S and another prosthesis were implanted survived the early period. They were followed for 764 patient-years. In this group the survival curve declined more rapidly (79±5.4, 47.6±7.7 and 20±6.4%, respectively).

Sudden death was observed in 46 of the 123 total deaths which occurred in the late follow up period (37.4%) (Table III).

The other causes of late mortality were cardiac failure, cerebrovascular thromboembolism and prosthetic valve endocarditis; 26.8% of the deaths were due to unknown causes (lack of information).

Valve related complications:

The mortality occurring during the operation is not directly related to the valve function if the surgical procedure is done properly. For this reason perioperative mortality was excluded from the evaluation of valve results. The valve related complications are generally accepted to be thromboembolism (TE), prosthetic valve endocarditis (PVE), valve thrombosis, periprosthetic leakage and anticoagulant related hemorrhage.

In our study, TE episodes are divided into 2 groups: neurological minor and major. Neurological manifestations such as vertigo, temporary weakness in the extremities and aphasia are considered as minor, and those requiring medical therapy and resulting in complications are considered as major neurological manifestations.

Hemorrhages developing due to the anticoagulation therapy are classified similarly. Gastrointestinal system bleeding requiring blood transfusion is considered as major, while metrorhagia and gingival bleeding are accepted as minor complications.

Thromboembolism:

In the early follow up period (n: 315), 9.5% of the cases had central, and 2.2% had peripheral TE complications (Table IV).

In the late period, when the cases were analyzed as a single group (n: 263), nonfatal TE was determined in 141 cases (53.6%). In 85 of them (32.3%), the TE event occurred during the first postoperative year. TE events recurred in 86 of the cases (32.7%). On an actuarial basis, 51.8± 4.6% of the patients were estimated to be free of TE events at 5 years (Fig. 5).

Of the 166 isolated MVR patients, 62 had TE events during the first year. Only 48.7% of the cases were TE-free at 5 years (Fig. 5). Forty six isolated MVR patients complained of recurrent TE episodes (27.7%).

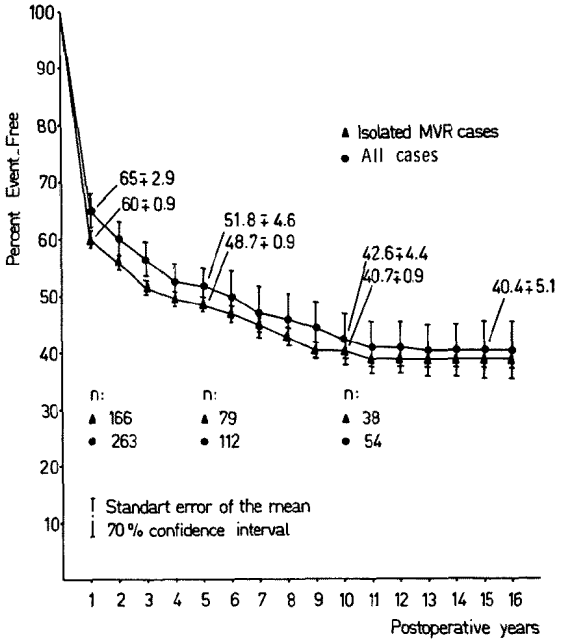

Fig. 5. Actuarial analysis of TE events in 2 groups of patients (isolated MVR and all cases).

Table IV. Valve Related Complications in the Early and Late Postoperative Periods

Complication	Early period (n: 315)	Late period (n: 263)
Thromboembolis	37(11.7%)	141(53.6%)
central TE	30 (9.5%)	124(47.1%)
peripheral TE	7 (2%)	17 (6.5%)
Prosthetic valve endocarditis	3 (0.9%)	4 (1.5%)
Valve failure	—	8 (3.0%)
Anticoagulant related hemorrhage (major)	4 (1.3%)	12 (4.6%)
Reoperation		6 (2.3%)

Prosthetic valve endocarditis (PVE):

In the early period, PVE occurred in 3 cases with fatal results (Table IV). Four patients were diagnosed as having PVE and treated accordingly in the late period. Infective agents could not be isolated in any of the cases.

Valve failure:

There was no periprosthetic leakage in any of the cases. In the late period, valve failures due to thrombosis were detected in 8 patients (3%), 6 of the valves were in tricuspid position (15.7% of total tricuspid implants)

Table V. Reoperations in the Late Period (n: 6)

Primary replacement	Reoperation interval	Etiology	Reoperation	Result
MVR (S-E) TVR (K-S)	13 years	Valve thrombosis	reTVR (C-E)	improved
MVR (S-E) TVR (K-S)	8 years	Valve thrombosis	reTVR (C-E)	improved
MVR (K-S)	5 years	Valve thrombosis	reMVR (L-K)	Exitus
MVR (K-S)	10 years	Multiple TE	reMVR (B-S)	improved
MVR (S-E) TVR (K-S)	8 years	Valve thrombosis	reTVR (C-E)	improved
MVR (K-S) TVR (K-S)	11 years	Valve thrombosis	reTVR (C-E)	Exitus

Abbreviations: (S-E)=Starr-Edwards; (L-K)=Lillehei-Kaster; (B-S)=Björk-Shiley; (C-E)=Carpentier-Edwards; (K-S)=Kay-Shiley.

and the other 2 in the mitral position (0.8% of total mitral implants). Three patients did not accept reoperation.

Reoperation:

Six cases were reoperated on in the late period (2.3%) (Table V). Two of the valves were in the mitral, and the remaining 4 in the tricuspid position. Reoperation indication was recurrent TE attacks in one of the MVR cases, and valve thrombosis in the rest. The reoperation mortality rate was 33%.

Discussion

Kay-Shiley valve prostheses were designed and constructed by Donald Shiley and Jerome H. Kay. Type I K-S valve consisting of a stellite ring, two parallel stellite struts and a silicone rubber disc was first used in 1965 to replace the tricuspid valve of a young man with Ebstein's anomaly.[2] A high thromboembolic rate encouraged modification to Type II valve in which the knitted teflon cloth was extended to reduce the area of exposed metal on the orifice. Type III prosthesis also included a guard projecting from the ring to inhibit ventricular muscle from interfering with blood flow and producing secondary obstruction and thrombosis. The guard was made 2 mm higher than the struts, and extended 230 degrees around the circumference (Fig. 6). In Type IV K-S, a second muscle guard was added and substitution of Delrin for silicon rubber as a disc material was used.[2)-4)] The most commonly used valve is Type I prosthesis. In all of our mitral cases, Type I prostheses were used.

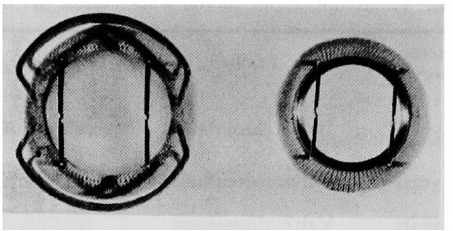

Fig. 6. The noncloth-covered Type I (right) and partially cloth-covered Type IV Kay-Shiley valve with two muscle guards (left).

The most commonly used valve size in the mitral position was 27 mm. It was reported in several studies[2),5),6)] that there was an 8.3–11 mmHg diastolic gradient at rest across these valves. On the other hand, the gradient was greater in the aortic position. Björk reported that there was a 28 mmHg gradient at rest, and a 37 mmHg one during exercise across the K-S valves in the aortic position.[2),7)] In our series postoperative gradient studies were not performed.

The annual TE rate of MVR cases was reported as 28% by Hughes and Carey,[9)] 23% by Brown et al[6)] and 30% by Vellons.[2)] Disregarding the early TE attacks, embolic episodes were observed in 60% of the cases. According to Cooley, the TE incidence was 14% per year.[6)] The TE incidence in our series was 11.7% in the early postoperative period and 32.3% in the first year. Emboli were generally related to the cerebral circulation. When cases are compared with those who underwent isolated MVR, it is observed that various types of prosthetic valve combinations slightly increase the TE risk, though this increase is not significant (Fig. 5). This result implies that the existence of the K-S valve is the main risk factor for TE in multiple valve replacements. A coexisting artificial valve does not increase the TE risk significantly.

The most common events which cause dysfunction of K-S valves are thrombosis, erosion of the disc and immobilization of the disc by fibrogranulomatous tissue ingrowth. In addition it was reported that movement of the disc can be interfered with by mural myocardium or papillary muscles.[2)] The most important reason for this is that the diameter of the disc is much larger than that of the orifice (23 mm versus 22 mm, respectively) (Fig. 7).

Strut and disc interference also causes disc erosion. In Fig. 8 it is seen that the disc erosion caused by strut trauma prevents proper function of the valve initially, and then fibrogranulomatous tissue development takes place.

The early mortality rate of isolated MVR cases is 29–33% in the literature.[2),5),6),8)] In Cooley's series of 130 cases, the operative mortality

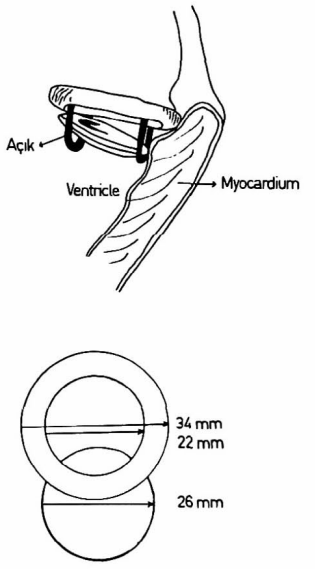

Fig. 7. Mechanism of disc impingement on the left ventricular endocardium with K-S valve.

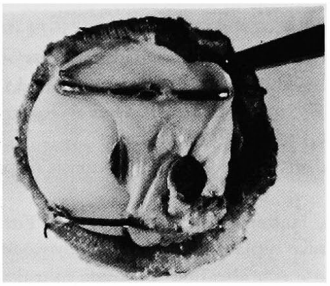

Fig. 8. Thrombotic K-S prosthesis (S.Y., pr.no.: 330427).

was 11%, and the mortality in the first year 17%.[6] Our early mortality rate was 10.8% in isolated MVR cases and total mortality 16.5% for all cases.

In the late follow up period the survival rates for 5 and 10 years were quite low (Fig. 4). Survival rates were lower in multiple valve replacements than in isolated MVR. Mortality was usually caused by thromboembolic complications.[10)-12)] In cases with multiple valve replacements, the fact that TE risk did not increase in spite of the increasing mortality rate suggests that the high mortality was due to myocardial dysfunction rather than valve-related factors. Twenty five percent of the deaths in the early period were due to cerebral emboli. In other words, 43.3% of the cerebral emboli were fatal. In addition, we noticed that in almost none of the cases

did a TE event occur after 10 years in the late follow up period (Fig. 5).

As a result, although the K-S valve was proposed as an alternative to caged-ball valves initially, it is no longer in use because of the high TE risk and high incidence of thrombosis and dysfunction of the valve. However, considering the late outcome of K-S and other outdated prostheses, it may contribute to the development of the ideal heart valve prosthesis in the future.

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