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Multicenter Analysis of Clinical Follow-Ups in Patients with a Star GK Cardiac Valve Replacement for More than One Year

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ABSTRACT

Background: Star GK valves were widely used in China, and we studied the clinical follow-up results of patients with Star GK valve implants for more than one year.

Methods: Clinical data were collected from those patients who had Star GK valve implants for over one year. Patients were divided into three groups: (1) AVR group: received aortic valve replacement surgery. Based on the valve model this group was further sub-divided into two groups: 21A group, and 23A group; (2) MVR group: received mitral valve replacement surgery. Based on the valve model this group was further sub-divided into three groups: 25M group, 27M group, and 29M group; (3) DVR group: received combined replacement surgeries including AVR + MVR. According to postoperative follow-up time these patients were divided into two groups: 1-year group and 3-year group. Follow-up data were collected by telephone, outpatient visits, or correspondence. Clinical data were aggregated by professional data scientists to conduct independent analyses.

Results: 959 patients were included in the study following Star GK valve implant. Follow-up after 1 year found that thrombosis occurred in 4 cases, hemorrhage in 15 cases, left heart failure in 13 cases, paravalvular leakage in 5 cases, and death due to cardiac causes in 2 cases.

Conclusion: The long-term efficacy of Star GK valve implants was satisfactory with low incidence of valve-related complications, and following Star GK valve implant, valve and blood were highly compatible and blood component damage was minor. Very low incidence rate of thrombosis was observed following Star GK valve implant, however, attention should be paid to adjust the anticoagulation intensity.

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INTRODUCTION

Heart valve disease is a common disease. Currently, valve replacement surgery is still the most effective means of

Table 1. Patient Characteristics and Perioperative Complications

	AVR group (n = 56)	MVR group (n = 493)	DVR group (n = 410)
Number of cases, n (%)	56 (8.4)	493 (49.3)	410 (42.3)
Age, y	48.40 ± 11.12	48.49 ± 10.31	48.49 ± 9.69
BSA, m^2	1.72 ± 0.88	1.74 ± 0.95	1.60 ± 0.74
Weight, kg	58.2 ± 8.37	67.49 ± 30.42	55.01 ± 12.85
Height, cm	164.10 ± 7.56	148.56 ± 42.88	151.46 ± 40.01
Postoperative intubation time, h	18.87 ± 10.63	21.25 ± 14.31	23.95 ± 16.25
ICU time, h	46.31 ± 21.11	53.56 ± 32.56	55.96 ± 30.94
Postoperative hospital stay, d	14.88 ± 4.91	16.58 ± 3.62	17.24 ± 4.20
Complications			
Low cardiac output	4 (7.1)	8 (1.6)	18 (4.4)
Respiratory complications	3 (5.35)	45 (9.1)	36 (8.8)
Renal failure	0	5 (1.0)	6 (1.5)
Nervous system complications	0	3 (0.6)	1 (0.2)
Wound infection	0	6 (1.2)	3 (0.7)
Multiple system and organ failure	3 (5.35)	7 (1.4)	16 (3.4)
Total	10 (17.8)	74 (15.0)	91 (19.0)

Data are presented as the mean ± SD where indicated. BSA indicates body face area; ICU, intensive care unit.

treatment [Kaneko 2014]. As one of the clinically common valve types used in mainland China, the GK valve did not have much clinically relevant literature about its efficacy. Commissioned by the Chinese Valve Clinical Research Domestic Expert Consensus Committee, national multi-center collaborative research was conducted to study the

Table 2. Biochemical, Cardiothoracic Ratio, and Echocardiographic Changes in MVR 25M Patients on Follow-Up

	MVR 25M 1-year group (n = 44)			MVR 25M 3-year group (n = 71)		
	Preoperative	Postoperative	*P*	Preoperative	Postoperative	*P*
HGB	96.89 ± 51.77	119.37 ± 38.09	.000	98.71 ± 49.71	116.30 ± 28.52	.000
CK	4.77 ± 1.85	3.97 ± 2.16	.238	4.42 ± 0.65	3.97 ± 1.51	.087
CK-MB	1.56 ± 0.73	1.42 ± 0.66	.532	1.63 ± 0.19	1.39 ± 0.39	.410
LDH	241.00 ± 206.11	159.17 ± 165.32	.023	239.88 ± 187.59	119.86 ± 123.40	.006
LDH-MB	7.03 ± 4.53	3.41 ± 2.38	.016	6.35 ± 3.82	6.00 ± 4.33	.167
H/C rate	0.58 ± 0.13	0.54 ± 0.07	.381	0.54 ± 0.18	0.41 ± 0.22	.000
LVEDD	45.68 ± 13.52	42.56 ± 12.92	.329	47.75 ± 14.05	43.67 ± 12.54	.545
LVESD	9.06 ± 15.69	7.07 ± 13.34	.420	39.02 ± 8.89	34.90 ± 13.70	.237
LVEF	57.53 ± 16.47	59.26 ± 20.10	.603	59.50 ± 12.60	59.63 ± 18.55	.961
LVFS	30.43 ± 10.90	30.01 ± 13.87	.824	28.42 ± 14.08	28.25 ± 14.96	.891
IVS	8.37 ± 2.79	7.88 ± 3.15	.347	8.45±2.25	9.01 ± 7.14	.493
MPG	31.97 ± 18.27	11.37 ± 8.91	.024	20.48 ± 10.49	8.48 ± 7.77	.000

Data are presented as the mean ± SD where indicated. HGB indicates hemoglobin; CK, creatine kinase; CK-MB, MB isoenzyme of creatine kinase; LDH, lactate dehydrogenase; LDH-MB, lactate dehydrogenase isoenzymes; H/C rate, cardiothoracic ratio; LVEDD, left ventricular diastolic internal diameter; LVESD, left ventricular internal diameter closed end; LVEF, left ventricular ejection fraction; LVFS, left ventricular shortening index; IVS, interventricular septum thickness; MPG, diastolic mitral transvalvular difference (mmHg).

Table 3. Biochemical, Cardiothoracic Ratio, and Echocardiographic Changes in MVR 27M Patients on Follow-Up

	MVR 27M 1-year group (n = 130)			MVR 27M 3-year group (n = 160)		
	Preoperative	Postoperative	*P*	Preoperative	Preoperative	*P*
HGB	101.43 ± 51.58	122.89 ± 48.80	.007	111.81 ± 49.97	124.30 ± 53.58	.000
CK	16.47 ± 21.96	15.38 ± 19.17	.420	11.47 ± 29.96	16.38 ± 39.17	.061
CK-MB	3.11 ± 5.33	1.66 ± 3.233	.013	2.42 ± 6.33	1.02 ± 3.66	.004
LDH	173.00 ± 117.65	93.63 ± 109.77	.000	176.00 ± 169.65	99.02 ± 137.31	.000
LDH-MB	38.90 ± 96.28	3.47 ± 8.11	.000	42.31 ± 103.45	0.56 ± 7.04	.000
H/C rate	0.57 ± 0.18	0.42 ± 0.25	.000	0.61 ± 0.62	0.40 ± 0.26	.000
LVEDD	49.26 ± 11.29	45.37 ± 9.66	.004	46.46 ± 11.35	51.55 ± 11.49	.000
LVESD	13.11 ± 17.42	22.82 ± 16.47	.807	11.21 ± 16.78	10.86 ± 15.51	.597
LVEF	60.80 ± 26.76	60.29 ± 15.20	.842	59.16 ± 15.45	61.77 ± 15.14	.129
LVFS	29.22 ± 11.11	30.93 ± 11.76	.074	29.88 ± 12.88	31.12 ± 13.38	.277
IVS	8.55 ± 2.57	7.83 ± 3.28	.026	8.44 ± 2.44	8.778 ± 2.9258	.150
MPG	20.35 ± 12.62	9.04 ± 10.18	.004	21.17 ± 10.32	8.68 ± 7.42	.002

Data are presented as the mean ± SD where indicated. HGB indicates hemoglobin; CK, creatine kinase; CK-MB, MB isoenzyme of creatine kinase; LDH, lactate dehydrogenase; LDH-MB, lactate dehydrogenase isoenzymes, H/C rate, cardiothoracic ratio; LVEDD, left ventricular diastolic internal diameter; LVESD, left ventricular internal diameter closed end; LVEF, left ventricular ejection fraction; LVFS, left ventricular shortening index; IVS, interventricular septum thickness; MPG, diastolic mitral transvalvular difference (mmHg).

clinical follow-up results of patients with Star GK valve implants for more than one year.

MATERIALS AND METHODS

Cardiac surgery data was collected as of June 2012 from the Third Military Medical University, Chongqing Xinqiao Hospital, Fujian Medical University Union Hospital, Second Xiangya Hospital, Central South University, Hunan, Shandong Jining Medical College Hospital, Henan Provincial Chest Hospital, Nanyang First Affiliated Hospital of Medical College, and Nanyang Central Hospital. Patients who had Star GK valve implants for more than a year and who met the clinical data inclusion criteria were included in the study. Patient inclusion criteria were: (1) had valvular surgery at one of the above seven hospitals between January 2006 and June 2012; (2) had Star GK valve replacement surgery more than a year prior; (3) had adverse events or death caused by cardiovascular or related issues (cancer or accidental adverse events were not included in this follow-up study); and (4) signed informed consent. Patients were grouped according to the type of implanted Star GK valves: (1) AVR Group: received aortic valve replacement surgery. Based on the valve model this group was further sub-divided into two groups: 21A group (No. 21A or below Star GK valves were implanted at the aortic position), and 23A group (No. 23A and above Star GK valves were implanted at the aortic position; (2) MVR group: received mitral valve replacement surgery. Based on the valve model this group was further sub-divided into three groups: 25M group (No. 25M Star GK valves were implanted at the mitral position, and 27M group (No. 27M Star GK valves were implanted at the mitral position, and 29M group (No. 29M and above Star GK valves were implanted at the mitral position; and (3) DVR group: received combined replacement surgeries including aortic valve replacement + mitral valve replacement. According to postoperative follow-up time these patients were divided into two groups: 1-year group (one to three years following surgery), and 3-year group (over three years following surgery). Follow-up data were collected via outpatient visits, telephone, or correspondence. After clinical data were aggregated, an independent analysis of the data was conducted.

RESULTS

959 patients were included in the study and following Star GK valve implant, perioperative complication incidence rates were between 15-19%. The common complications included low cardiac output syndrome, respiratory tract infections, respiratory failure, wound infection, multiple organ failure, renal failure, and nervous system accidents. Details are shown in Table 1. Follow-up after 1 year found that thrombosis occurred in 4 cases (0.42%), hemorrhage in 15 cases (1.56%), infective endocarditis in one case (0.10%), left heart failure in 13 cases (1.36%), lower extremity edema in 29 cases (3.02%), syncope in five cases (0.52%), paravalvular leakage in 5 cases (0.52%), and death due to cardiac causes in 2 cases (0.21%).

The No. 25M Star GK mitral valve implant one-year follow-up group included 44 patients. Biomarker LDH and LDH-MB were significantly lower ($P < .05$) following

Table 4. Biochemical Changes in MVR 29M Patients on Follow-Up

	MVR 29M 1-year group (n = 37)			MVR 29M 3-year group (n = 42)		
	Preoperative	Postoperative	*P*	Preoperative	Postoperative	*P*
HGB	112.01 ± 67.29	131.52 ± 19.65	.024	110.01 ± 49.31	124.50 ± 19.65	.048
CK	47.31 ± 39.54	30.21 ± 36.57	.360	37.46 ± 75.01	20.07 ± 35.09	.130
CK-MB	6.41 ± 7.38	4.22 ± 6.57	.326	5.90 ± 6.76	3.65 ± 6.33	.090
LDH	149.00 ± 156.59	113.65 ± 121.83	.029	189.00 ± 126.77	82.38 ± 116.85	.000
LDH-MB	39.05 ± 54.27	11.50 ± 8.79	.019	78.05 ± 94.35	12.53 ± 9.62	.000
H/C rate	0.65 ± 0.27	0.51 ± 0.17	.366	0.58 ± 0.28	0.44 ± 0.30	.000
LVEDD	55.11 ± 9.67	48.72 ± 7.20	.000	48.87 ± 9.719	47.89 ± 18.78	.996
LVESD	31.60 ± 15.69	28.90 ± 14.07	.007	39.83±16.27	37.08 ± 17.92	.200
LVEF	58.67 ± 13.06	58.89 ± 9.18	.924	53.55 ± 22.89	58.75 ± 17.02	.197
LVFS	40.99 ± 9.72	38.35±7.81	.650	26.76 ± 16.28	30.21 ± 13.72	.151
IVS	7.81 ± 3.86	6.238 ± 4.94	.034	8.58 ± 3.11	7.48 ± 4.00	0.067
MPG	34.83 ± 47.19	10.28 ± 15.91	.003	17.76 ± 19.45	10.48 ± 8.07	.029

Data are presented as the mean ± SD where indicated. HGB indicates hemoglobin; CK, creatine kinase; CK-MB, MB isoenzyme of creatine kinase; LDH, lactate dehydrogenase; LDH-MB, lactate dehydrogenase isoenzymes, H/C rate, cardiothoracic ratio; LVEDD, left ventricular diastolic internal diameter; LVESD, left ventricular internal diameter closed end; LVEF, left ventricular ejection fraction; LVFS, left ventricular shortening index; IVS, interventricular septum thickness; MPG, diastolic mitral transvalvular difference (mmHg).

surgery, while hemoglobin increased significantly ($P < .01$). Cardiac ultrasound showed mitral transvalvular pressure was 11.37 ± 8.91 mmHg, which is significantly lower than the preoperative level ($P < .05$). There were 71 patients in the No. 25M Star GK mitral valve implant 3-year follow-up group in whom LDH decreased significantly following surgery ($P < .01$), while hemoglobin was significantly higher ($P < .01$) and cardiothoracic ratio was reduced significantly ($P < .01$). Cardiac ultrasound showed that mitral transvalvular pressure was 8.48 ± 7.77 mmHg, significantly lower when compared with the preoperative levels ($P < .01$) (Table 2).

There were 130 cases in the No. 27M Star GK mitral implant one-year follow-up group that revealed that LDH and LDH-MB fell significantly ($P < .01$) when compared to preoperative levels, while CK-MB was significantly lower ($P < .05$) and hemoglobin increased significantly ($P < .05$). Cardiothoracic ratio and left ventricular diastolic diameter were found to be significantly lower ($P < .01$) following surgery. Septal thickness decreased significantly ($P < .05$). Mitral transvalvular pressure was 9.04 ± 10.18 mmHg, significantly lower than the preoperative level ($P < .01$). There were 160 cases in the No. 27M Star GK mitral valve implant 3-year follow-up group whose CK-MB, LDH, and LDH-MB were reduced significantly ($P < .01$), while hemoglobin increased significantly following surgery ($P < .01$) and cardiothoracic ratio dropped significantly ($P < .01$). Left ventricular diastolic internal diameter also fell significantly ($P < .01$). Mitral transvalvular pressure was 8.68 ± 7.42 mmHg, significantly ($P < .01$) lower than preoperative levels as shown in Table 3.

There were 37 cases in the No. 29M Star GK mitral valve implant one-year follow-up group. The decrease of biomarker LDH and CK-MB were significantly lower than preoperative levels ($P < .05$), while hemoglobin increased significantly ($P < .05$). Left ventricular systolic diameter was reduced significantly ($P < .01$). Mitral transvalvular pressure was 10.28 ± 15.91 mmHg, significantly lower than preoperative levels ($P < .01$). There were 42 patients in the No. 29M Star GK mitral valve implant 3-year follow-up group in whom LDH and LDH-MB were reduced significantly following surgery ($P < .01$), while hemoglobin significantly increased ($P < .05$). Cardiothoracic ratio decreased significantly ($P < .01$) and mitral transvalvular pressure was 10.48 ± 8.07 mmHg, significantly lower than the preoperative level ($P < .01$) as seen in Table 4.

The Star GK combined valve implant one-year follow-up group had 172 cases and following surgery, CK and LDH-MB levels decreased significantly ($P < .01$), along with CK-MB and LDH levels ($P < .05$). Hemoglobin increased significantly ($P < .01$), while left ventricular diastolic diameter and left ventricular systolic diameter reduced significantly ($P < .01$). Septal thickness was also found to be significantly lower than prior to surgery ($P < .01$). The mitral and aortic transvalvular pressure were 8.26 ± 16.18 mmHg and 18.97 ± 22.50 mmHg, respectively, significantly lower than preoperative levels ($P < .01$). There were 237 cases in the Star GK combined valve implant 3-year follow-up group, where CK, CK-MB, LDH, and LDH-MB levels decreased significantly compared to the preoperative levels ($P < .01$). Hemoglobin increased significantly ($P < .01$), while cardiothoracic ratio

Table 5. Biochemical, Cardiothoracic Ratio, and Echocardiographic Changes in DVR Group during Follow-Up

	DVR 1-year group (n = 172)			DVR 3-year group (n = 237)		
	Preoperative	Postoperative	*P*	Preoperative	Postoperative	*P*
HGB	107.16 ± 63.43	131.35 ± 39.98	.000	110.76 ± 48.47	128.53 ± 42.10	.000
CK	44.12 ± 48.46	15.33 ± 25.37	.000	35.84 ± 50.90	14.07 ± 58.70	.000
CK-MB	3.87 ± 5.11	2.34 ± 4.53	.015	2.52 ± 5.40	1.46 ± 5.60	.000
LDH	198.43 ± 96.55	106.55 ± 45.37	.042	132.58 ± 136.39	98.76 ± 91.63	.000
LDH-MB	41.58 ± 75.71	7.43 ± 4.39	.003	47.8 ± 106.35	5.66 ± 2.09	.000
H/C rate	0.60 ± 0.13	0.51 ± 3.56	.716	0.60 ± 0.39	0.49 ± 0.45	.004
LVEDD	53.51 ± 11.37	44.29 ± 14.43	.000	51.91 ± 14.49	47.24 ± 10.16	.000
LVESD	32.01 ± 18.22	19.50 ± 15.56	.004	30.99 ± 17.77	30.03 ± 16.33	.160
LVEF	59.31 ± 10.94	58.46 ± 19.88	.594	58.84 ± 12.95	62.65 ± 13.03	.001
LVFS	31.12 ± 10.16	31.53 ± 12.95	.665	30.47 ± 10.48	32.84 ± 11.11	.001
IVS	8.74 ± 3.26	7.40 ± 4.22	.000	9.11 ± 2.37	9.41±2.32	.099
MPG	21.62 ± 12.03	8.26 ± 16.18	.001	20.49 ± 22.20	7.15 ± 11.89	.046
APG	35.23 ± 30.43	18.97 ± 22.50	.002	30.84 ± 26.58	15.25 ± 13.71	.001

Data are presented as the mean ± SD where indicated. HGB indicates hemoglobin; CK, creatine kinase; CK-MB, MB isoenzyme of creatine kinase; LDH, lactate dehydrogenase; LDH-MB, lactate dehydrogenase isoenzyme; H/C rate, cardiothoracic ratio; LVEDD, left ventricular diastolic internal diameter; LVESD, left ventricular internal diameter closed end; LVEF, left ventricular ejection fraction; LVFS, left ventricular shortening index; IVS, interventricular septum thickness; MPG, diastolic mitral transvalvular difference (mmHg).

was reduced significantly (P < .01). Left ventricular diastolic diameter was significantly lower (P < .01), while EF and FS increased significantly (P < .01). The mitral and aortic transvalvular pressure were 7.15 ± 11.89 mmHg and 15.25 ± 13.71 mmHg, respectively, significantly lower than preoperative levels (P < .01) as seen in Table 5.

The No. 21A Star GK aortic valve implant had 17 cases in which following surgery, hemoglobin increased significantly (P < .05), while cardiothoracic ratio and septal thickness were significantly lower (P < .05). Aortic transvalvular pressure was 20.42 ± 17.51 mmHg, significantly lower following surgery (P < .01). There were 39 cases in the No. 23A Star GK aortic valve implant. In the postoperative follow-up, it was found that LDH, LDH-MB, CK, and CK-MB were significantly lower (P < .05). Meanwhile, cardiothoracic ratio, left ventricular diastolic diameter, and septal thickness were significantly lower as well (P < .01). Aortic transvalvular pressure was 15.64 ± 16.30 mmHg, significantly lower than the pressure before surgery (P < .01) as seen in Table 6.

DISCUSSION

Patient Characteristics

Before the surgery, patients in this study were in critical condition. There were two types of patients in this study. Some patients had poor preoperative cardiac function and were in critical condition, thus requiring emergency surgery. These patients' heart function and general condition cannot be corrected or improved in the short term. The other patients suffered from economic difficulties and the surgery wasn't performed within the proper window of time. These patients experienced prolonged and severe illness, most with pulmonary hypertension, tricuspid lesions, huge left atrium, left atrial thrombus, etc. They had a history of recurrent heart failure and when hospitalized their heart function was at the III-IV grade. The outcome of heart valve replacement surgery is often related to factors such as the severity of the disease [Reid 2014; Sims 2006]. In addition, atrial fibrillation can significantly affect hemodynamics and cardiac function, and can cause damage related to secondary thrombosis [Sims 2006; McCarthy 2010]. 74.42% of patients had persistent and refractory AF. Due to economic and other reasons, only 11 (1.15%) patients underwent atrial fibrillation intervention. This may impact patient recovery, long-term efficacy, and complications.

Efficacy of GK Valve Implants

The study included 959 patients who met the inclusion criteria. The overall outcomes were satisfactory. After the implant of Star GK valves, the perioperative complication rate was 15-19%. Common perioperative complications were low cardiac output syndromes, respiratory complications, wound infections, multiple organ failure, renal failure, nervous system and other accidents. There was no significant difference between these occurrences and the early complications with other types of valves [Reid 2014].

When followed up for 1 year or more, patients experienced cardiothoracic ratio decrease in comparison to the preoperative level. Cardiac ultrasound showed left ventricular systolic

Table 6. Biochemical, Cardiothoracic Ratio, and Echocardiographic Changes in AVR Group during Follow-Up

	AVR 21A group (n = 17)			AVR 23A group (n = 39)		
	Preoperative	Postoperative	*P*	Preoperative	Postoperative	*P*
HGB	101.36 ± 52.47	128.18 ± 44.07	.000	93.33 ± 62.17	128.89 ± 55.78	.000
CK	3.23 ± 4.14	3.03 ± 5.08	.765	6.02 ± 7.79	3.76 ± 8.63	.279
CK-MB	94.76 ± 121.20	50.78 ± 90.33	.020	120.09 ± 93.68	67.11 ± 114.12	.014
LDH	83.83 ± 106.21	15.66 ± 19.03	.015	14.86 ± 17.45	6.89 ± 9.04	.000
LDH-MB	101.36 ± 52.47	128.18 ± 44.07	.000	93.33 ± 62.17	128.89 ± 55.78	.000
H/C rate	0.60 ± 0.04	0.43 ± 0.26	.042	0.59 ± 0.27	0.39 ± 0.29	.03
LVEDD	53.83 ± 9.49	37.28 ± 23.16	.056	63.05 ± 14.19	53.24 ± 11.60	.000
LVESD	30.99±22.80	27.03 ± 16.33	.909	38.00 ± 24.03	31.84 ± 20.83	.003
LVEF	44.68 ± 28.95	54.75 ± 14.56	.239	51.44 ± 13.55	53.87 ± 15.90	.432
LVFS	30.47 ± 10.48	32.84 ± 14.11	.845	24.27 ± 12.82	25.84 ± 14.44	.215
IVS	19.18 ± 40.59	14.52 ± 17.09	.041	20.41 ± 13.29	15.04 ± 20.62	.047
APG	32.02 ± 21.00	20.42 ± 7.51	.001	23.57 ± 6.35	19.01 ± 13.60	.048

Data are presented as the mean ± SD where indicated. HGB indicates hemoglobin; CK, creatine kinase; CK-MB, MB isoenzyme of creatine kinase; LDH, lactate dehydrogenase; LDH-MB, lactate dehydrogenase isoenzyme; H/C rate, cardiothoracic ratio; LVEDD, left ventricular diastolic internal diameter; LVESD, left ventricular internal diameter closed end; LVEF, left ventricular ejection fraction; LVFS, left ventricular shortening index; IVS, interventricular septum thickness; MPG, diastolic mitral transvalvular difference (mmHg).

or diastolic diameter were significantly reduced, while no significant improvement was observed with EF and FS. This was possibly because patients undergoing valve replacement surgery were still at the decompensation stage. Mitral transvalvular pressure is considered an important echocardiographic metric to evaluate the prosthetic valve functions [Blauwet 2007]. With 1-3 years of follow-up, the group implanted at the mitral position with the No. 25M, 27M, and 29M GK valves had a mitral transvalvular pressure of 11.37 ± 8.91 mmHg, 9.04 ± 10.18 mmHg, and 10.28 ± 15.91 mmHg, respectively. For follow-up of more than 3 years, mitral transvalvular pressure was 8.48 ± 7.77 mmHg, 8.68 ± 7.42 mmHg, and 10.48 ± 8.07 mmHg, respectively. For the combined valve replacement group, 1-year and 3-year follow-up showed that the aortic transvalvular pressure was 18.97 ± 22.50 mmHg and 15.25 ± 13.71 mmHg, respectively. For the aortic valve replacement group, the No. 21A and the 23A valve implant patients were followed up for 1 year or longer. Their aortic transvalvular pressure was 20.42 ± 17.51 mmHg and 19.01 ± 13.60 mmHg. All these outcomes were regarded satisfactory. It is believed that the use of larger valves may be more conducive to the recovery of patients after surgery, although the relevant supporting evidence was limited [Pibarot 2008; Gillinov 2003]. In case patients and valves mismatch, the valve size can be determined by the size of the annulus and heart.

The incidence of valve-related complications was low more than one year after surgery. The embolism rate was 0.42%, hemorrhage rate 1.56%, infective endocarditis incidence rate 0.10%, left ventricular failure rate 1.36%, lower extremity edema incidence 3.02%, syncope rate 0.52%, paravalvular leak rate 0.52%, and no patients had valvular dysfunction. There were two cases of death due to cardiac causes (0.21%). No significant difference was observed between the occurrence of common complications of these implants and that of other types of valves [Sims 2006].

After the implant of the valves, valve-human compatibility is very important. We used warfarin as the anticoagulant and the standard INR was maintained between 1.8 and 2.5. Our results showed that the embolism incidence rate was 0.42%, lower than what was reported in the literature [Moraca 2009]. Bleeding rate was 1.56%, suggesting that when GK Star valves are used on Chinese patients, attention should be paid to adjust the dosage of standard anticoagulant and to lower the anticoagulation intensity. After one year or more follow-up, this group's patients' hemoglobin increased and no obvious damage to blood visible components was observed. These results suggested that GK Star had better valve-human compatibility.

Limitations

The present study is retrospective and not randomized. Furthermore, follow-up duration is relatively short, and a longer follow-up is required.

Conclusion

This multicenter study revealed the following: (1) The long-term efficacy of Star GK valve implants was satisfactory with low incidence of valve-related complications; (2) We also observed very low incidence rate of thrombosis following Star GK valve implant, however, attention should be paid to adjust the anticoagulation intensity; (3) Following Star GK valve implant, valve and blood were highly compatible and blood component damage was minor; (4) With the Star GK valve implants, mitral and aortic transvalvular pressure were low, with mitral transvalvular pressure at approximately 10 mmHg and aortic transvalvular pressure at approximately 20 mmHg.

Conclusion

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