MEDICAL SCIENCE MONITOR

CLINICAL RESEARCH

e-ISSN 1643-3750
© Med Sci Monit, 2015; 21: 2542-2546
DOI: 10.12659/MSM.894044

Received: 2015.03.08
Accepted: 2015.05.05
Published: 2015.08.27

Star GK Bileaflet Mechanical Valve Prosthesis-Patient Mismatch After Mitral Valve Replacement: A Chinese Multicenter Clinical Study

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Source of support: This work was supported by Chinese national and Fujian provincial key clinical specialty construction programs

Background: The aim of this study was to investigate the incidence and immediate and mid-term effects of heart valve prosthesis-patient mismatch (PPM) after mitral valve replacement using the GK bileaflet mechanical valve.

Material/Methods: A total of 493 cases of mechanical mitral valve replacement were performed in the departments of cardiac surgery in 7 hospitals from January 2000 to January 2008. The patients included 142 men and 351 women ages 21 to 67 (average age, 48.75). The patients were followed for 3 years after surgery. The effective orifice area index (EOAI), ≤1.2 cm^2/m^2, was detected during the follow-up period and was defined as PPM. The patients were assigned to either the PPM group or the non-PPM group. Finally, the preoperative, perioperative and postoperative indexes of the 2 groups of patients were compared.

Results: A total of 157 patients had PPM 3 years after surgery. The incidence of PPM was 31.84%. Sixty-three patients in the PPM group received a 25-mm GK bileaflet valve (40.13%), 82 received a 27-mm valve (52.23%), and 12 (7.64%) received a 29-mm valve. There were significant differences in length of intensive care unit stay, duration of ventilator use, length of hospitalization, body surface area, EOAI, mean transmitral pressure gradient, and pulmonary artery pressure between the PPM and non-PPM group ($P<0.05$). There was a significant difference between preoperative and postoperative pulmonary artery pressures among non-PPM patients ($P<0.05$); however, there was no statistical difference in preoperative and postoperative pulmonary artery pressures among patients with PPM ($P>0.05$).

Conclusions: PPM after mitral valve replacement influences postoperative hemodynamics. Thus, larger-sized GK bileaflet mechanical valves are often used to reduce the risk of PPM.

MeSH Keywords: Bioprosthesis • Mitral Valve • Pulmonary Artery

Full-text PDF: http://www.medscimonit.com/abstract/index/idArt/894044

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Background

Heart valve prosthesis-patient mismatch (PPM) occurs when the effective orifice area index (EOAI) of a heart valve prosthesis is less than that of the normal heart valve. After implantation of a heart valve prosthesis, a relatively narrow valve opening leads to a series of complications and risks [1]. In recent years, PPM after mitral valve replacement has attracted more and more attention from researchers. We studied the prevention of PPM by retrospectively analyzing mitral valve replacement with GK bileaflet mechanical valve implantation in 493 adults. We followed the patients for 3 years after surgery, analyzing the preoperative, perioperative, and postoperative indexes of the 2 groups of patients and preliminarily exploring the reasons behind the formation of postoperative PPM.

Material and Methods

Patients

Study subjects included 493 patients with valvular heart diseases who underwent mitral valve replacement in the departments of cardiac surgery in 7 hospitals (Union Hospital of Fujian Medical University, Second Affiliated Hospital of Third Military Medical University, Second Xiangya Hospital of Central South University, Jining Medical College Affiliated Hospital, Henan Provincial Chest Hospital, Affiliated Hospital of Nanyang Medical College, and Nanyang Municipal Central Hospital) from January 2000 to January 2008. Patients who had concomitant aortic valve replacement were excluded. Of the subjects, 142 were men and 351 were women. They were 21 to 67 years old (average age, 48.75 years). Of them, 323 had rheumatic heart disease, 105 had a degenerative heart disease, 56 had infective endocarditis, and 9 had ruptured mitral valve chordae. All subjects underwent mitral valve replacement surgery with implantation of different sizes of GK bileaflet mechanical valves. Patients with tricuspid incompetence or an enlarged left atrium concomitantly underwent tricuspid annuloplasty or left atrial plication. All subjects returned to the hospital after 3 years and underwent echocardiography. The mitral valve EOAI in cm^2 was detected using the continuity equation method, and the EOAI cm^2/m^2 was calculated according to body surface area. PPM was defined as EOAI ≤ 1.2 cm^2/m^2, and subjects were assigned to either the PPM group (n=157) or the non-PPM group (n=336).

Surgical method

Surgery was performed under conditions of intravenous-inhalation compound anesthesia, moderate temperature and hemodilution, and extracorporeal circulation with cardiac arrest. Blood cardioplegia was used for perfusion. A chest median incision was performed, and catheters were placed in the aorta and upper and inferior vena cava to establish extracorporeal circulation. The subvalvular structures of the mitral valve were explored through the pathway of the right atrium, atrial septum, and mitral valve. The mitral valve was removed, the size of the valve annulus was measured with a suitable measuring device, and EOAI expected value was calculated according to body surface area. The appropriate size of prosthetic valve was selectively used, and the prosthetic valve was implanted using double-needle and gasket interrupted mattress suture. Patients with tricuspid incompetence or an enlarged left atrium concomitantly underwent tricuspid annuloplasty or left atrial plication.

Monitoring parameters and methods

The Vivid7 Dimension Color Doppler Ultrasound System (GE Healthcare) was used to measure hemodynamic parameters such as left ventricular ejection fraction, mean transmitral pressure gradient, mitral valve EOAI, and pulmonary pressure.

Data sources

Preoperative and perioperative data were obtained through review of the medical records. Follow-up data was obtained when all 493 patients returned to the hospital to undergo echocardiography to measure relevant parameters to determine cardiac function.

Statistical methods

SPSS16.0 software was used for statistical analysis. Measurement data were expressed as mean standard deviation, and a paired t-test was performed. The count data were expressed as frequency, and the chi-square test, Fisher's exact test, or a test using the continuity correction formula was conducted. $P<0.05$ was considered statistically significant.

Results

Depending on whether postoperative PPM was present, the patients were assigned to the PPM group or the non-PPM group. In this study, the incidence of PPM was 31.84%. Sixty-three patients (40.13%) received a 25-mm valve, 82 (52.23%) received a 27-mm valve, and 12 (7.64%) received a 29-mm valve. There were no significant differences in the preoperative indexes between the 2 groups ($P>0.05$) (Table 1). During the perioperative period, there were significant differences in length of intensive care unit (ICU) stay, duration of ventilator use, and length of hospitalization between the PPM and non-PPM group ($P<0.05$) (Table 2). Follow-up data 3 years after surgery showed statistical differences in body surface area, EOAI,

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Table 1. Preoperative patient data.

	PPM group (n=157)	Non-PPM group (n=336)	*P* value
Sex (male/female)	40/117	102/234	0.27
Age (x±s years)	48.30±11.93	48.52±9.36	0.83
Body surface area (x±s m^2)	1.61±0.40	1.63±0.35	0.42
Causes			
Rheumatic heart disease	91	232	0.11
Degenerative diseases	42	63	
Infective endocarditis	21	35	
Ruptured mitral valve chordae	3	6	
Preoperative parameters by echocardiography			
EF (x±s%)	58.39±14.03	60.95±31.05	0.22
Mean transmitral pressure gradient (x±s mmHg)	31.71±7.14	29.17±9.35	0.08
Mean pulmonary artery pressure (x±s mmHg)	58.32±9.17	59.07±11.21	0.13

Table 2. Various perioperative indexes.

	PPM group (n=157)	Non-PPM group (n=336)	*P* value
25-mm GK valve	63	46	
27-mm GK valve	82	193	<0.01
29-mm GK valve	12	97	
CPB time (x±s min)	81.37±13.17	79.35±18.26	0.08
Length of intensive care unit stay (x±s min)	61.67±39.98	51.17±29.68	<0.01
Time of ventilator use (x±s h)	23.63±12.86	20.35±14.05	0.04
Length of hospitalization (x±s d)	24.41±6.19	14.28±9.73	<0.01

mean transmitral pressure gradient, and mean pulmonary artery pressure between the PPM and non-PPM group ($P<0.05$) (Table 3). The preoperative and postoperative mean pulmonary artery pressures in the PPM group were 58.32±9.17 mm Hg and 53.29±10.63 mm Hg, respectively ($P>0.05$). The preoperative and postoperative mean pulmonary artery pressures in the non-PPM group were 59.07±11.21 mm Hg and 43.17±12.17 mm Hg, respectively ($P>0.05$) (Table 4).

Discussion

Until now, most research on PPM has focused on PPM after aortic valve replacement surgery. In 1981, Rahimtoola et al. reported 1 case of PPM with persistent pulmonary hypertension and right heart failure after mitral valve replacement surgery. Since then, more and more in-depth studies have been conducted on PPM after mitral valve replacement [2–5]. In the present study, the incidence of PPM after mitral valve replacement surgery was 31.84%, which is lower than the data reported in other relevant studies in the literature [6,7]. This difference may be related to the short stature, light weight, and small corresponding surface area of people living in southern China.

Causes of PPM formation

In our study, 63 subjects had PPM after implantation of 25-mm GK bileaflet mechanical valves, while 82 subjects had PPM after implantation with 27-mm GK bileaflet mechanical valves. These 2 groups accounted for 92.36% of total patients with PPM. In theory, if the condition of the mitral annulus permits, a larger-sized heart valve prosthesis is used. However, most patients with mitral valve replacement have rheumatic heart disease (65.52%); thus, the long-term changes of rheumatism lead to adhesion, fusion, and even calcification of the mitral annulus, resulting in a smaller valve annulus and left ventricular atrophy. If the larger-sized heart valve prosthesis is implanted, valve movement may be constricted and serious

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Table 3. Relevant indexes of follow-up 3 years after surgery.

	PPM group (n=157)	Non-PPM group (n=336)	*P* value
Body surface area (x±s m^2)	1.69±0.11	1.65±0.07	0.02
EOAI (x±s cm^2/m^2)	1.14±0.03	1.27±0.02	0.01
Postoperative parameters by echocardiography			
EF (x±s%)	53.75±21.17	58.09±22.37	0.07
Mean transmitral pressure gradient (x±s mm Hg)	25.34±6.35	14.89±5.77	<0.01
Mean pulmonary artery pressure (x±s mm Hg)	53.29±10.63	43.17±12.17	<0.01

Table 4. Comparison of preoperative and postoperative mean pulmonary artery pressures between the PPM group and non-PPM group.

	Preoperative mean pulmonary artery pressure (x±s mm Hg)	Postoperative mean pulmonary artery pressure (x±s mm Hg)	P value
PPM group	58.32±9.17	53.29±10.63	0.07
Non-PPM group	59.07±11.21	43.17±12.17	<0.01

complications such as a ruptured left ventricular posterior wall or arrhythmia can occur.

However, valve annulus enlargement is seldom performed for the mitral valve; thus, when the body surface area is relatively large but the valve annulus measured during surgery is small, the surgeon is forced to choose a 25-mm or 27-mm GK bileaflet mechanical valve. After valve replacement, cardiac function and quality of life improves. At the same time, the patient's weight, and thus body surface area, increases. Meanwhile, factors such as invasion of the surrounding tissue, pannus growth, and even thrombosis growth on the mechanical valve annulus can lead to decreased mechanical valve EOAI. This results in mismatches between the valve EOAI and the body surface area, and formation of PPM.

Effect of PPM on hemodynamics

PPM after mitral valve replacement leads to a degree of mitral stenosis. Pathophysiological changes include a high transvalvular pressure gradient, corresponding increased left atrial pressure and pulmonary hypertension, left atrial enlargement, pulmonary edema, and right heart failure, which affect the cardiac output. In this study, duration of ventilator use, length of ICU stay, and length of hospitalization were longer in the PPM group than in the non-PPM group ($P<0.05$). Because postoperative hemodynamics are not completely improved, it affects postoperative recovery. Pulmonary artery pressure in the PPM group was not decreased after surgery compared with the non-PPM group ($P>0.05$), while pulmonary artery pressure in the PPM group was significantly decreased after surgery ($P<0.05$). These findings were similar to the reports of Raghuveer et al. [8] and Li M et al. [9], indicating that PPM leads to sustained increases in pulmonary artery pressure and affects the function of the tricuspid valve, which may result in right ventricular dysfunction and the appearance of symptoms such as abdominal distension and swelling of the lower limbs.

PPM prevention

Despite much research, PPM remains difficult to prevent. In our experience, body surface area is calculated before surgery and an appropriately sized valve is selected based on the EOAI expected value. However, when the valve annulus is observed to be small during surgery, the subvalvular tissue structures are removed to the extent possible, a relatively large-sized prosthetic valve is implanted, intraoperative transesophageal echocardiography is performed, and various indices are monitored to prevent or reduce the degree of PPM. Currently, mechanical valves of superior quality are being studied; these valves simultaneously have excellent hemodynamics and a larger EOAI (e.g., the type M-2 mechanical valve).

Conclusions

In our study subjects, the much larger body surface area after surgery indicated that patients should control their weight and be physically active to avoid PPM. The valvuloplasty should be applied, when possible, in surgical treatment of mitral and tricuspid valve diseases. After mitral valvuloplasty, patients have stable hemodynamics and larger EOAIs. The incidence of PPM

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is significantly lower than that occurring after mitral valve replacement, but the technical difficulty of mitral valvuloplasty is relatively greater in terms of the disease type in China. However, more studies are now being done in countries other than China [10,11], which will improve mastery of the surgical indications and operative technique.

This study has some limitations. It was a retrospective analysis of medical records and the total number of cases was low, with confounding factors and the lack of a prospective study with a large number of cases.

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