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Original Article

Beating-heart versus conventional mitral valve replacement; a randomized clinical trial

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Abstract

Background: Various methods have been developed to overcome the deleterious effects of ischemia/ reperfusion injury that occurs after cardioplegic arrest. The aim of the study was to assess the safety, efficacy, and applicability of the beating-heart mitral valve replacement (MVR) compared to the conventional MVR.

Methods: Forty patients scheduled for mitral valve replacement were randomly assigned into two groups, conventional MVR as the control group (n= 20) and beating-heart MVR with continuous antegrade coronary perfusion as the study group (n=20). Three patients in the beating-heart group were converted to the conventional technique because of the blood-flooded field and excluded from the analysis.

Results: The preoperative clinical and echocardiographic variables were comparable between both groups. There was no significant difference between both groups regarding cardiopulmonary bypass time (79.4± 14 vs. 75.7± 10.9 minutes; p= 0.398) and total operative time (200± 55.6 vs. 183.9± 67.5 min; p= 0.458) in the conventional and beating-heart group, respectively. Serum troponin I level was significantly higher in the conventional MVR group 6 hours postoperatively (4.9±4 vs. 2.7±1.2 ng/ml; p= 0.036), while there was no significant difference between both groups regarding total CK and CK-MB (p= 0.565 & 0.597 respectively). Eight patients (44%) in the conventional MVR group needed inotropic support compared to 3 patients (19%) in the beating-heart MVR group (P = 0.11). There was no operative mortality or major morbidity in both groups. At 6-months follow-up, there was no difference in NYHA class (1.3±0.3 vs. 1.2±0.3; p= 0.336) and the ejection fraction (60.0±6.3 vs. 63.2±6 %; p= 0.139) in the conventional vs. beating-heart group.

Conclusion: Beating-heart MVR is a safe alternative to the conventional method with comparable outcomes. There is a relatively blood-filled field compared to the conventional technique.

KEYWORDS

Beating heart; Cardioplegic arrest; Mitral valve replacement

Article History

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Introduction

Conventional mitral valve surgery is performed under cardioplegic arrest and aortic cross-clamp with a well-established efficacy and safety [1]. However, ischemia/ reperfusion injury remains a potential complication of the operation. Therefore, various methods and solutions have been developed to overcome the deleterious effects of ischemia/reperfusion injury [1–4]. These effects can be more prominent in patients with

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impaired ventricular function and right ventricular hypertrophy. Lack of sufficient oxygen delivery to the myocardium during the ischemic period may lead to low cardiac output syndrome [1].

Recently, the use of the beating-heart technique was extended to valve surgery with satisfactory outcomes [1-4]. It seems reasonable to use on-pump beating heart technique for heart valve surgery if myocardial perfusion is maintained and particulate or air embolism is avoided.

The advantage of beating mitral valve surgery is still debatable. The aim of this study was to assess the safety, efficacy, and applicability of the beating-heart mitral valve replacement (MVR) compared to the conventional MVR.

Patients and Methods:

This study is a randomized trial that was conducted in our center from March 2017 to April 2019, after approval of the local Ethics Committee and written consent was obtained from all patients.

Inclusion criteria were adult patients who had rheumatic or degenerative mitral valve disease scheduled for a mitral valve replacement with or without concomitant tricuspid valve intervention. We excluded patients who had concomitant procedures, and end-organ severe dysfunction, including hepatic failure, chronic renal failure, and previous stroke. Patients who had surgery for infective endocarditis and those with prior cardiac surgery were excluded.

Computer-generated numbers randomly assigned patients into two groups: conventional MVR as the control group and beating-heart MVR with continuous coronary perfusion (CCP) as the study group. Fifty-eight patients were assessed for eligibility criteria; 18 of them were excluded before randomization (10 patients were not meeting inclusion criteria, and 8 declined to participate in the study). Three patients in the beating heart MVR group were converted to the conventional technique because of the blood-flooded field and were excluded from the analysis. Three patients, two in the conventional MVR group and one in the beating-heart MVR group, were lost for follow-up and excluded from the analysis. (Figure 1)

Preoperative evaluation included a detailed history, clinical examination, routine laboratory investigations and cardiac enzymes, electrocardiography (ECG), chest X-ray, and cardiac catheterization when indicated. Preoperative transthoracic echocardiography (TTE) was performed for all patients to assess mitral valve, tricuspid valve, left atrial dimension, pulmonary artery pressure, left ventricular end-diastolic dimension (LVEDD), left ventricular end-systolic dimension (LVESD), and left ventricular ejection fraction (EF). Preoperative transesophageal echocardiography (TEE) was done for 12 patients to assess the possibility of mitral valve repair.

Operative procedures

The standard general anesthetic technique for open-heart surgery with routine arterial and venous monitoring was used for both groups. A midline sternotomy approach was used for all patients. After full heparinisation, ascending aorta, superior and inferior vena cave cannulation were performed. The cardioplegic cannula was inserted in the ascending aorta as usual, and a vent was inserted through the right superior pulmonary vein into the left atrium. Then cardiopulmonary bypass (CPB) was established. The cardioplegic cannula in the beating-heart MVR group was connected through the insertion of a Y-shaped line to the arterial perfusion line of the CPB pump oxygenator.

Conventional MVR (control group):

The ascending aorta was cross-clamped between the arterial perfusion cannula and the cardioplegic cannula with a vascular aortic clamp. Intermittent antegrade warm blood hyperkalemic cardioplegia was used, and repeated doses were administered every 20-25 minutes. Mean arterial pressure was maintained between 60 and 80 mmHg with a pump flow rate between 2 - 2.5 L / min / m2. Mitral valve replacement using everting interrupted sutures with Teflon pledged with preservation of the posterior mitral leaflet was performed through the left atrial approach.

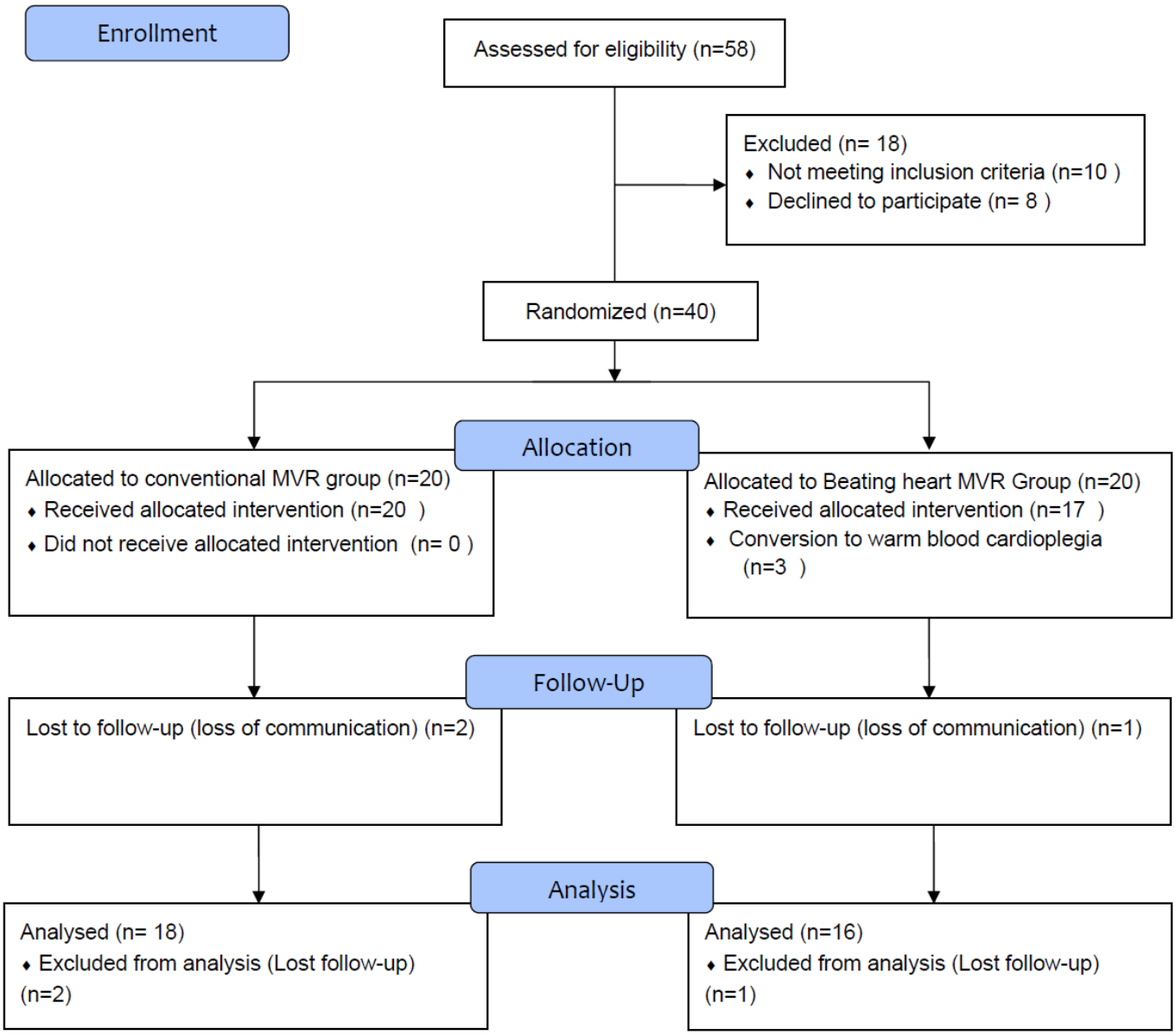

Figure 1: Study Flow Diagram

Bileaflet mechanical mitral valve prostheses were used in all patients. Concomitant tricuspid valve repair was done under beating heart for patients who had moderate or more tricuspid regurgitation (n= 9). Modified DeVega annuloplasty was used in all patients.

Beating-heart MVR (study group):

As in the conventional MVR group, ascending aorta was cross clamped between the arterial perfusion cannula and the cardioplegic cannula with a vascular aortic clamp after initiation of CPB, and the cavae were snared. Venting blood from the left side started through the right superior pulmonary vein vent that was inserted. Continuous perfusion of the coronary arteries was maintained with oxygenated blood from the CPB pump oxygenator through the connected "cardioplegic" cannula. Body temperature was kept at 36°C - 37°C, and the mean systemic pressure maintained above 60 - 80 mmHg with a pump flow rate between 2 - 2.5 L / min / m2. Aortic valve competency is essential for continuous perfusion of the coronary arteries.

We used the transseptal approach for mitral valve replacement to avoid the tension of retraction on the atrial wall that may cause aortic incompetence and flooding the field with blood. The right atrium was opened longitudinally. A suction catheter was introduced to the right ventricle through the tricuspid valve to vent the

Table 1: Preoperative variables of the patients. Continuous variables are presented as mean ± SD and categorical variables as number and percent.

Variables		Conventional MVR Group (n=18)	Beating heart MVR Group (n=16)	p-value
Age (years)	Mean ± SD	37.1±7.7	33.3±8.6	0.193
	(range)	25-50	20-50	
Sex, Female		12(67%)	12(75%)	0.44
NYHA		3.3±0.4	3.2±0.4	0.469
Echo Data	EF%	60±6.4	62.2±6.8	0.343
	LVEDD (cm)	5.5±0.9	5.3±0.9	0.519
	LVESD (cm)	3.7±0.8	3.5±0.8	0.469
	LA (cm)	5.8±1	5.4±0.8	0.20
	PASP (mmHg)	51.6±16.2	49.9±12.7	0.738
MV Lesion	MS	4(22%)	3(19%)	0.571
	MR	6(33%)	7(44%)	0.393
	MS and MR	8(45%)	6(37%)	0.476
Rhythm	Sinus	2(11%)	4(25%)	0.271
	AF	16(89%)	12(75%)	

MVR = Mitral Valve Replacement, NYHA = New York Heart Association class, EF = Ejection Fraction, LVEDD = Left Ventricular End Diastolic Dimension, LVESD = Left Ventricular End Systolic Dimension, LA = Left Atrial Dimension, PASP = Pulmonary Artery Systolic Pressure, MS = Mitral Stenosis, MR = Mitral Regurgitation, AF = Atrial Fibrillation.

right ventricle and to keep tricuspid valve incompetent. Fossa ovale incised longitudinally, and the incision extended superiorly toward the superior vena cava and inferiorly to the area behind coronary sinus accessing the left atrium with direct exposure of the mitral valve. The interatrial septum was retracted with standard mitral retractor exposing the mitral valve. The venting catheter was redirected to the left ventricle through the mitral valve to vent the left ventricle and keep it empty.

Mitral valve replacement with bileaflet mechanical mitral valve prosthesis was done with the heart beating. The technique of MVR was the same as that done in the conventional MVR group. With the beginning of fixing the prosthetic valve and tying its sutures, the vent was redirected to the left atrium, and the mitral valve prosthesis was kept open with a small-sized Foley catheter. After the fixation of the prosthetic valve, the left ventricle was filled with blood to extrude the air through the opening mitral valve prosthesis. Tricuspid annuloplasty was carried out with a modified DeVega technique for patients in 8 patients. Cross clamp time, CPB time, and total operative time were recorded for all patients in both groups.

Postoperative assessment

Serum enzymes (total CK, CK-MB, and Troponin I) concentration were measured and recorded at 6 hours postoperatively for all patients. Duration of mechanical ventilation, inotropic support, total blood loss, units of blood transfused, duration of intensive care unit (ICU), and hospital stays were recorded for all patients. Postoperative complications that occurred during hospital stay were managed and recorded for all patients. Pre-discharge, trans-thoracic echocardiography (TTE) was done for all patients, and its data were recorded. The pre-discharge cardiac rhythm was recorded for all patients.

Follow up

Patients were followed-up for six months in the outpatient clinic, and TTE was done for all patients at six months postoperatively.

Table 2: Intraoperative and postoperative data. Continuous variables are presented as mean ± SD and categorical variables as number and percent.

Variables			Conventional MVR Group (n=18)	Beating heart MVR Group (n=16)	p-value
Intra-operative	Cross-clamp time, min		41.6±9.4	42.6±8	0.739
	CPB time, min		79.4±14	75.7±10.9	0.398
	Total operative time, min		200±55.6	183.9±67.5	0.458
Postoperative Data	Cardiac enzymes	CK total (U/L)	632.5±119.6	654.9±106.4	0.565
		CK -MB (U/L)	57.6±36.4	52.6±14.8	0.597
		Troponin I (ng/ml)	4.9±4	2.7±1.2	0.036
	Need for Inotropic support		8(44%)	3(19%)	0.11
	Drain, ml		445±129.6	512.5±123.4	0.13
	Blood units		1.4±0.8	1.6±0.8	0.469
	Mechanical ventilation, hours		9±3.3	8.4±2.6	0.564
	I.C.U, days		2.2±0.4	2.1±0.2	0.352
	Hospital stay, days		12.3±1.8	12.2±3	0.91

Ao= Aortic. CPB= cardiopulmonary bypass; CK total= total creatine phosphokinase; CK –MB = creatine-phosphokinase isoenzyme-muscle brain fraction; Drain = total blood loss in the drainage system; I.C.U = intensive care unit.

Statistical Analysis

Continuous variables were presented as mean ± standard deviation (SD) and categorical variables as numbers and percentages. Chi-square test or Fischer Exact test if the frequency of the events was less than five were used for comparison between categorical variables and continuous variables were compared using t-test or Mann–Whitney test if not normally distributed. The difference was considered significant at a p-value of less than 0.05. Analyses were done using IBM SPSS for Windows, Version 23.0 (IBM Corp. Chicago, IL USA).

Results

There was no significant difference in age (p = 0.193), gender (p = 0.44) and NYHA class (p= 0.469) between groups. (Table 1) Preoperative echocardiographic data were comparable between groups. (Table 1) Atrial fibrillation (AF) was the predominant rhythm in both groups with no significant difference (P = 0.271). (Table 1)

Table 3: Postoperative complications. Categorical variables are presented as number and percent.

Variables	Conventional MVR Group (n=18)	Beating heart MVR Group (n=16)	p-value
PSVT	3(17%)	0	0.136
Wound infection	1(5.5%)	1(6%)	0.727
Re-exploration for bleeding	1(5.5%)	1(6%)	0.727
Cerebrovascular stroke	0	1(6%)	0.47
Prolonged mechanical ventilation	1(5.5%)	0	0.529
Total	6(33%)	3(19%)	0.285
Patients without complications	12(67%)	13(81%)	0.285

PSVT = paroxysmal supra-ventricular tachycardia

Intraoperative data

Conversion from beating heart technique to the conventional technique occurred in 3 patients (15%); conversion occurred because the retraction to visualize the mitral valve induced aortic incompetence causing flooding the field with blood. The conversion was smooth without complication in the three patients.

There was no significant difference between the conventional MVR group and beating heart MVR group regarding aortic cross-clamp, CPB time, and total operative time (P = 0.739, 0.398 and 0.458 respectively). (Table 2)

Postoperative outcomes

Serum troponin I level was significantly higher in the conventional MVR group 6 hours postoperatively (P = 0.036). At the same time, there was no significant difference between both groups regarding total CK and CK-MB (p = 0.565 & 0.597, respectively). Forty-four percent of patients in the conventional MVR group needed inotropic support compared to only 19% in beating heart MVR group; however, there was no statistically significant difference (P = 0.11). (Table 2)

There was no significant difference between both groups regarding total blood loss, duration of mechanical ventilation support, units of blood transfusion, duration of ICU, and hospital stay. (Table 3)

In the conventional MVR group, one patient had re-exploration for bleeding (5.5%), 3 patients (17%) had paroxysmal supraventricular tachycardia (PSVT), one patient had superficial wound infection (5.5 %), and one patient (5.5%) had prolonged mechanical ventilation for more than 24 hours due to chest infection. In beating-heart MVR group, one patient had re-exploration for bleeding (6%), one patient had superficial wound infection (6%), and one patient (6%) had a non-disabling cerebrovascular stroke (CVS). There was no significant difference between both groups regarding total numbers of complications (p = 0.285). There was no mortality in both groups.

Pre-discharge TTE

Results showed no significant difference between both groups regarding EF (p = 0.15), LVEDD (P = 0.476), LVESD (P = 0.218), LA dimensions (P = 0.333) and PASP (P = 0.703). (Table 4) All mitral valve prostheses in both groups were well seated and well-functioning. There was no significant difference regarding cardiac rhythm between both groups (P = 0.271) with a predominance of AF rhythm (89% of patients in the conventional MVR group and 75% in beating heart MVR group).

Follow-up

Patients had regular follow-up visits in the outpatient clinic for six months postoperatively. Three patients, two in the conventional MVR group and one in beating heart MVR group, were lost for follow-up. TTE was done for all enrolled patients (n= 34) 6 months after surgery. There was no significant difference between both groups regarding left ventricular function and dimensions, left atrial dimension, and pulmonary artery systolic pressure. (Table 5) NYHA functional class improved in both groups as compared to preoperative values without significant difference between both groups (P = 0.336).

Discussion

Beating heart techniques have expanded to include the mitral valve to decrease the risk of ischemic/reperfusion injury [5]. The technique may be of importance to those with left or right ventricular dysfunction who are more prone to myocardial damage during the ischemic time [6]. The on-pump beating-heart technique for heart valve surgery is feasible if myocardial perfusion is maintained, and particulate or air embolism is avoided [7,8].

With a competent aortic valve, the heart continues to be perfused through the aortic root without clamping the ascending aorta. The left heart is kept empty and vented to the atmosphere, so there is a pressure gradient between aorta and left ventricle keeping the aortic valve closed, the heart beating, and left ventricle cannot push blood, air or particulate to aorta [8,9]. Morfa and coworkers [10] modified the technique by cross-clamping the ascending aorta between the aortic cannula and the cardioplegic cannula

Table 4: Pre-discharge echocardiography and cardiac rhythm. Continuous variables are presented as mean ± SD and categorical variables as number and percent.

	Variables	Conventional MVR Group (n=18)	Beating heart MVR Group (n=16)	p-value
Echo Data	EF (%)	59.0±5.9	62.1±6.2	0.15
	LVEDD (cm)	5.4±0.9	5.2±0.7	0.476
	LVESD (cm)	3.7±0.8	3.4±0.6	0.218
	LA (cm)	5.2±1.0	4.9±0.8	0.333
	PASP (mmHg)	46.6±14.1	44.9±11.6	0.703
Rhythm	Sinus	2(11%)	4(25%)	0.271
	AF	16 (89%)	12(75%)	

ECHO= Echocardiography; EF=ejection fraction; LVEDD= left ventricular end-diastolic dimension; LVESD= left ventricular end-systolic dimension; LA= left atrial dimension; PASP = Pulmonary artery systolic pressure A. F= atrial fibrillation

that connected to the arterial perfusion line of CPB pump oxygenator. Therefore, continuous perfusion of the coronary arteries is maintained with oxygenated blood from the CPB pump oxygenator. We used this modified technique in this study. With incompetent aortic valves, there is another option for doing valvular heart surgery on beating heart, using retrograde perfusion of the heart through the coronary sinus and cross-clamping the ascending aorta with venting the aortic root [1, 7, 11].

The surgical approach to the mitral valve is performed either using the conventional left atrial approach [3, 9, 12] or transseptal approach [1, 11, 13]. We used the transseptal approach in this study as recommended by Salerno and colleagues [13] because retraction of the left atrial wall during the trans-atrial approach often caused aortic insufficiency, for this reason, they shifted from trans-atrial to transseptal approach.

Table 5: Six-month follow-up. Continuous variables are presented as mean ± SD and categorical variables as number and percent.

	Variables	Conventional MVR Group (n=18)	Beating heart MVR Group (n=16)	p-value
Echo Data	EF (%)	60.0±6.3	63.2±6	0.139
	LVEDD (cm)	4.9 ±0.8	4.8±0.7	0.697
	LVESD (cm)	3.3±0.7	3.1±0.5	0.342
	LA (cm)	4.8±1.0	4.3±1.2	0.204
	PASP (mmHg)	43.4±12.1	41.9±10.8	0.704
Rhythm	Sinus	2(11%)	4(25%)	0.271
	AF	16(89%)	12(75%)	
NYHA		1.3±0.3	1.2±0.3	0.336

ECHO= Echocardiography; EF=ejection fraction; LVEDD= left ventricular end-diastolic dimension; LVESD= left ventricular end-systolic dimension; LA= left atrial dimension; PASP = Pulmonary artery systolic pressure A. F= atrial fibrillation, NYHA = New York Heart Association class.

Although we used the transseptal approach for exposure of mitral valve, 3 patients (15%) in the beating heart MVR group were converted to the conventional technique with warm blood cardioplegia because of flooding the field with blood by induced aortic incompetence with retraction. The conversion was easy without complication. Mo and coworkers [11] reported the conversion of 7 patients (2.8%), and Elsherif and collaborators [3] reported the conversion of one patient (3.3%) due to flooding the field with blood and difficulty to deal with the contracting annulus. With all efforts to obtain a bloodless field with the technique of beating-heart valve surgery, this approach still causes a relatively blood-filled field compared to conventional mitral valve surgery [14].

Cellular damage markers, total CK, CK-MB, and troponin I, increased 6-hour postoperatively in both groups. There was no significant difference in the levels of total CK and CK-MB, but troponin I level was significantly lower in the beating-heart MVR group (P= 0.036). Our results coincide with the results of Katircioglu and colleagues [15] who reported significantly lower levels of CK-MB and troponin-T in the beating-heart group. Morfa and coworkers [10] reported lower levels of total CK and CK-MB in the beating group compared to the conventional group, despite the absence of a significant difference between the two groups. These results indicate that cellular damage always occurs due to CPB, regardless of the type of myocardial protection used, and there is lesser cellular damage with beating heart technique. This technique provides continuous perfusion of the cardiac muscles and avoids the effects of ischemia/reperfusion injury.

In our study, 44% of the patients in the conventional MVR group needed inotropic support compared to 19% in the beating-heart MVR group. That coincides with the finding of Babaroglu and coworkers [9] who reported 35% vs 16% in the conventional group and beating group, respectively, and the findings reported by Katircioglu and co-investigators [15] who reported the 7.9% in the beating-heart mitral valve surgery needed inotropic support. The above results could be attributed to lesser cardiac cellular damage with beating heart surgery.

In our study, there was no significant difference between both groups regarding aortic cross-clamp time, the total bypass time, and total operative time. However, the mean total operative time in the beating-heart group was lesser by about 16 minutes. These findings coincide with the results reported by Morfa and colleagues [10]. This finding can be explained by the absence of reperfusion time needed for support and weaning from CPB in the beating group.

Katircioglu and coworkers [15] reported that cerebral stroke occurred in one (1.1%) patient. Salerno and colleagues [1] in a study of 291 patients reported a 6.8% 30-day mortality rate, and 4 (1.3%) patients had a stroke. Pasic and coworkers [2] in their retrospective study on 120 consecutive patients underwent beating-heart mitral valve surgery who were at high-risk for conventional mitral valve surgery reported no intraoperative deaths, a 7.5% 30-day mortality rate, and the main complications were prolonged mechanical ventilation (40%), pneumonia (25%), multiorgan failure (10%), acute kidney injury (7.5%) and disabling stroke (2.5%). In our study, there was no operative mortality or major morbidity in both groups; one patient (6%) had a non-disabling cerebrovascular stroke in the beating group. These results coincide with the results reported by Morfa and coworkers [10], and this is because all the patients included in both studies were low surgical risk.

Follow up of the patients at 6-months postoperatively showed improvement in NYHA functional class and the echocardiographic data in both groups without significant differences between them. These improvements are mostly attributed to the replacement of the diseased mitral valve.

Study limitations

The study has several limitations, including the small number of patients and the exclusion of all high-risk patients. Additionally, the study

represents a single-center experience. A larger study in high-risk patients is recommended.

Conclusion

Beating mitral valve replacement with continuous antegrade perfusion of the coronary arteries without cardioplegia usage seems to be an acceptable alternative to the conventional technique. There is a relatively blood-filled field compared to the conventional technique.

Conflict of interest: Authors declare no conflict of interest.

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