

Effectiveness of early cardiac rehabilitation in patients with heart valve surgery: a randomized, controlled trial

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Abstract

Objective: Complications of heart valve surgery lead to physical inactivity and produce harmful effects. This study aimed to investigate the role of a cardiac rehabilitation program and its long-term effect in patients after heart valve surgery.

Methods: We performed a single-blind, randomized, controlled trial. Patients with heart valve surgery were randomly assigned to receive early cardiac rehabilitation (intervention group, 44 patients) or the usual care (control group, 43 patients). The intervention group performed sitting, standing, and walking exercises, followed by endurance training. The control group received usual care and did not engage in any physical activity. Physical function was assessed by the Short Physical Performance Battery (SPPB) and other measurement tools.

Results: The intervention group showed a significant beneficial effect regarding physical capacity as shown by the SPPB and the 6-minute walking test at hospital discharge, and a better long-term effect was achieved at 6 months compared with the control group. An improvement in physical function (e.g., the SPPB) after hospital discharge predicted follow-up mortality (odds ratio = 0.416, 95% confidence interval: 0.218–0.792).

Conclusion: Early cardiac rehabilitation appears to be an effective approach to improve the physical function and survival of patients with heart valve surgery.

Keywords

Coronary artery disease, heart valve surgery, early cardiac rehabilitation, physical function, mental health, short physical performance battery, exercise

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The trial was retrospectively registered in the ISCTRN database (reference number: ISRCTN54158701).

Introduction

Valvular heart disease is a major and growing public health issue accompanied by population aging and a lengthy life expectancy in developing countries. Heart valve surgery is a well-established procedure worldwide with excellent cardiovascular benefits, quality of life, and mortality rates.¹ However, patients who have heart valve surgery often experience complications in the postoperative period because of the complexity of the procedure, including low cardiac output syndrome, postoperative bleeding, infection, and difficulty in glycemic control.^{2,3}

Complications in the postoperative period of heart valve treatment increase sedation and bed rest,⁴ leading to an extended period of physical inactivity and muscle weakness.⁵ The harmful effects of physical inactivity involve reduced muscle protein synthesis, increased proteolysis, and loss of muscle strength and lean mass.^{6–8} These issues prevent patients from fully returning to a normal functional ability⁸ and increasing the risk of readmission and mortality.^{9,10}

The importance of adequate physical activity has been stressed by clinical guidelines.¹¹ Physical activity and exercisebased cardiac rehabilitation are thought to increase cardiorespiratory fitness and reduce long-term cardiac mortality and short-term hospitalization in patients with coronary heart disease.^{12–14} Additionally, physical exercise is associated with reduced respiratory complications, decreased loss of muscle strength, and a decline in hospital readmission rates in patients with coronary heart disease.^{15–17} Therefore, exercise-based cardiac rehabilitation is recommended after heart valve surgery to increase physical capacity and improve clinical outcomes.

Maintaining adequate physical activity for patients who have heart valve surgical treatment may be challenging and causes safety issues outside the hospital. Therefore, exercise-based cardiac rehabilitation should be considered in these patients. Recently, early cardiac rehabilitation was applied to patients with cardiac surgery in the in-hospital setting,¹⁸ and it decreased the duration of the hospital stay and medical costs after cardiac surgery.^{19,20} However, the role of early cardiac rehabilitation on physical and psychological functions and its long-term effects on patients who have heart valve surgery have not been fully determined.

This study aimed to investigate the role of early cardiac rehabilitation in physical and psychological function and its longterm effects in patients with heart valve surgery. Early cardiac rehabilitation was performed in the hospital setting on the day after the operation.

Methods

Participants

The was a prospective study that was performed in a hospital setting. The sample size was calculated by the difference between two independent means (two groups) using G*Power software (version 3.1.9.7; Heinrich-Heine-University, Düsseldorf, Germany),²¹ using the following parameters: alpha = 0.05, power $(1-\beta) = 0.80$, and effect size = 0.7. The sample size was determined to be 37 patients or more in each group. Considering a possible dropout of 10%, the final sample size was determined to be 40 patients or more in each group. Ninetyseven consecutive patients who had heart valve surgery performed were enrolled in the study between January 2018 and December 2019 (Figure 1). The inclusion

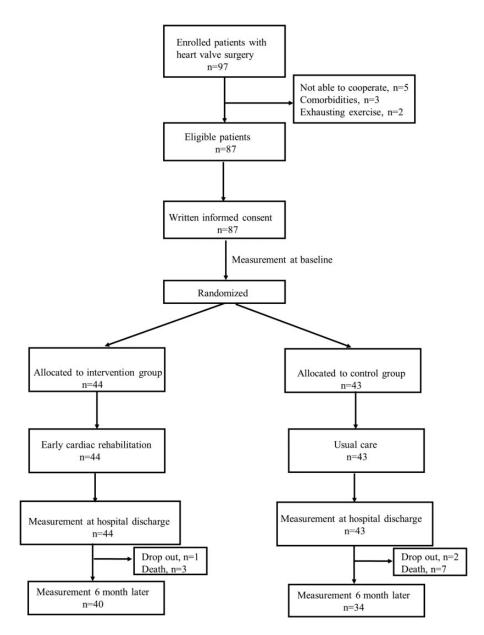


Figure 1. Flowchart showing patient selection for participation in early cardia rehabilitation.

criteria were elective left-sided or rightsided heart valve surgery, including aortic, mitral, tricuspid, and pulmonary valve replacement, >18 years old, and being able to understand and complete measurements and provide informed written consent. One experienced physician performed the assessment for eligibility. The exclusion criteria were ischemic heart disease before surgery, diseases in the musculoskeletal system, comorbidity complicating physical activity, and an expectation to not 4

cooperate in the trial instructions. Patients who had persistent or paroxysmal atrial fibrillation diagnosed by Holter electrocardiography preoperatively were excluded from this study. Patients who underwent an emergency surgical treatment or transcatheter aortic valve implantation were also excluded. The study was approved by the Medical Ethics Committee of Anhui Medical University (Hefei City, China; 2018: approval number: Januarv 4. AHMULS20180465) and complied with the Declaration of Helsinki. The trial was retrospectively registered in the ISCTRN database (ISRCTN54158701, http://www. isrctn.com/).

Randomization

The early cardiac rehabilitation program was conducted in a randomized, controlled trial (RCT), which followed the CONSORT statement (http://www.consort-statement. org/). Patients were grouped by simple random sampling. The randomization program was created using a computer and performed by an investigator who was not involved in the treatment and recruitment of patients. The allocation of patients was screened, and allocations were placed in numbered, sealed, opaque envelopes. On the first day of treatment after surgery, the envelope that was allocated to the patient was unfolded by the physical therapist. Patients were randomly assigned to two groups of those who received cardiac rehabilitation (intervention group) or those who received the usual care (control group). Before surgery (baseline), at hospital discharge, and after 6 months of followup, the physical capacity and psychological status were measured. Blinding of the participants and clinicians is usually inconceivable in a rehabilitation trial. Nonetheless, outcome assessment, data management, and statistical analyses were performed with blinding to the allocation groups.

Intervention and controls

Implementation of this study followed the StaRI statement of the Equator Network (https://www.equator-network. guideline org/). The intervention group underwent the cardiac rehabilitation program from the day following surgery in accordance with a clinical guideline for rehabilitation in patients with cardiovascular disease.²² This rehabilitation exercise program comprised lower and upper extremity exercise in bed, sitting on the edge of the bed, standing at the bedside, and walking around the bed and for 100 m in the ward. The exercise included four sessions lasting for 4 days, three times a day, with approximately 30 minutes each time. After the rehabilitation exercise, patients continued with gait practice for up to 500 m and carried out endurance training by using a stationary bike in the rehabilitation center of the hospital. The training session took place three times a day with approximately 30 minutes each time until they were discharged from the hospital. The intensity of physical activity was limited by clinical conditions and activity tolerance, and monitored and assisted by physical therapists. The control group did not participate in any rehabilitation program and only received routine clinical care during the duration of the hospital stay.²²

Data collection

The investigators assessed all patients on the day before surgery (baseline assessment), the day of hospital discharge, and 6 months after hospital discharge.

Primary measurement: physical function. The Short Physical Performance Battery (SPPB) was used to evaluate physical function.²³ The SPPB is a useful and well-established tool for assessing the physical ability of elderly people,.²⁴ The SPPB

consists of a timed 4-minute walking test, a five-repetition sit-to-stand test, and a set of standing balance.²³ Each measurement was assigned a score ranging from 0 to 4. The total scores (0–12) were used to obtain an overall measurement of physical function. The SPPB is advantageous and has been widely used in the clinical setting.^{25,26}

Secondary measurement: mental health. The mental health of patients was measured with a mental component summary (MCS) from the 12-item Short-Form Health Survey,²⁷ as recommended by a previous study.²⁸

Six-minute walking test and other physical and mental measurements. We performed the 6-minute walking test (6MWT), which involved measurement of the 6-minute walking distance and is a submaximal functional test indicative of performing daily activities.²⁹ The safety and feasibility of this test have led to its use in cardiovascular rehabilitation.³⁰ The physical component summary (PCS) from the 12-item Short-Form Health Survey and the Hospital Anxiety and Depression Scale were also included as self-reported measurements.

Outcome measurements: readmission and mortality. After 6 months of hospital discharge, all-cause readmission and mortality as outcome measurements were collected from the clinical records and follow-up investigation by the research team.

Statistical analysis. The intention-to-treat analysis was recommended in the RCT.³¹ For outcomes of patients who withdrew from the trial, an intention-to-treat analysis was performed using the last value (e.g., at the time point of hospital discharge) obtained for each of the outcome measures. Finally, normality was examined by the Kolmogorov–Smirnov test. Data are expressed as mean with standard deviation for continuous variables (e.g., SPPB, PCS, MCS, and 6MWT) and as the frequency and percentage for categorical variables (e.g., sex, type of valve, readmission, and mortality). Group comparisons of categorical variables were carried out with the chisquare test. Comparisons of continuous variables between the two groups were performed using the independent sample t-test and repeated analysis of variance. Age, sex, the length of hospital stay, and types of surgery were selected as confounding factors. Differences with a two-sided p value of <0.05 were considered significant. Post-hoc analysis was adjusted by Bonferroni multiple comparison correction. Logistic regression analysis was also performed to assess the predictive effects of the main measurement variables on clinical outcomes (e.g., readmission and mortality). All statistical analyses were performed using IBM SPSS version 21.0 (IBM Corp., Armonk, NY, USA).

Results

Baseline characteristics

After applying the inclusion and exclusion criteria, 87 patients were included in this study and met the sample size requirements. There were 44 patients in the intervention group and 43 in the control group. One patient in the intervention group and two in the control group dropped out after 6 months of follow-up. The patients' characteristics are shown in Table 1. The mean age of the participants in the intervention and control groups was 58.20 ± 5.27 and 57.98 ± 4.18 years, respectively. The majority of the intervention group (65.91%) and the control group (62.79%) were men. All patients had heart valve disease, but primarily had a ortic valve stenosis (43%) and mitral valve regurgitation (35%). The percentages of patients in the invention and control groups who completed the trial 6

	Invention group	Control group			
Characteristics	(n = 44)	(n = 43)	$t(\chi^2)$	Þ	
Sex, male/female	29/15	27/16	0.09	0.761	
Age, years	$\textbf{58.20} \pm \textbf{5.27}$	$\textbf{57.98} \pm \textbf{4.18}$	0.23	0.824	
BMI, kg/m ²	$\textbf{23.09} \pm \textbf{2.23}$	$\textbf{23.28} \pm \textbf{2.59}$	0.363	0.717	
Systolic blood pressure, mm Hg	130-170	132-180	0.893	0.422	
Diastolic blood pressure, mm Hg	77-100	75–100	1.235	0.121	
Total cholesterol, g/L	0.046-0.011	0.047-0.011	0.764	0.413	
Symptoms before surgery, n	32	31	0.07	0.948	
Type of heart valve, n			0.16	0.992	
Aortic valve	30	31			
Mitral valve	8	7			
Other ^a	6	5			
Hypertension	28	27	0.07	0.936	
Hypercholesterolemia	19	16	0.32	0.570	
Postoperative LVEF, %	51-10	52–11	0.857	0.413	

Table 1. Demographic and clinical characteristics of the participants.

Values are mean $\pm\, {\rm standard}$ deviation, number, or range.

^aOther includes concomitant aortic and mitral valve surgery or right-sided valves.

BMI, body mass index; LVEF, left ventricular ejection fraction.

were 90.91% and 79.07%, respectively. The demographic and clinical variables did not differ between the two groups, which suggested no evidence of baseline imbalances.

Effectiveness of early cardiac rehabilitation

Repeated analysis of variance analysis showed that SPPB scores improved over time, and the mean improvement was greater in the intervention group than in the control group (F = 9.55, p < 0.001). Moreover, there was a significant main effect of mean SPPB scores between the intervention and control groups (F = 5.40, p = 0.002, Table 2). Post-hoc comparison showed that patients in the intervention group showed a significant improvement in physical function (SPPB) at hospital discharge (mean difference = 1.07 \pm 1.89, p = 0.001, effect size = 0.380) and after 6 months of follow-up (mean difference- $= 1.16 \pm 2.73$, p = 0.023, effect size = 0.323) compared with those in the control group (Table 2). The Cohen's d of the crude mean

difference in physical function (SPPB) between the groups was 0.819 and 0.682 at hospital discharge and after 6 months, respectively. These values were >0.50, which indicated a moderate clinical effect and a long-term effect.

Similarly, physical outcomes, including the PCS score and 6MWT distance, showed a significant improvement in the intervention group at hospital discharge and at 6 months of follow-up compared with those at baseline (Table 2). In addition, the intervention group showed a shorter length of stay in the hospital compared with that in the control group (t = 8.30, p < 0.001; Table 3). However, the Hospital Anxiety and Depression Scale and MCS scores were not significantly different between the two groups at different time points (Table 2).

Effect of variables on outcomes

In regression analysis, age, sex, the type of surgery, and physical functional

	Intervention group	ď		Control group			Between-group comparison	1-group son
	Baseline $(n=44)$	Hospital discharge $(n = 44)$	After 6 months $(n = 40)$	Baseline $(n = 43)$	Hospital discharge $(n = 43)$	After $6 months$ $(n = 34)$	ш	¢
SPPB	8.86 ± 1.52	10.18±1.28	10.11 ± 1.70	8.74 ± 1.83	9.09 ± I.38	8.95 ± 1.70	5.40	0.002
þ	0.684	0.001	0.023				- L L	
ۍ ۲	+0.00 ± 3.04 0.417	0.299 ± 0.04	0.00 ± 01.10 0.001	10.03 ⊞ 0.32 -	01./ ⊞ 17.C 1 _	00.1 ∐ 00.0 1 –	10.0	700.0
MCS	46.45 ± 7.04	$\textbf{50.16} \pm \textbf{6.47}$	51.75 ± 8.05	47.58 ± 7.16	48.79 ± 7.19	$\textbf{48.14} \pm \textbf{8.47}$	1.29	0.283
þ	0.329	0.292	0.110	I	I	I		
6MWT (m)	311.52 ± 54.98	360.36 ± 60.26	415.50 ± 65.68	309.58 ± 57.44	316.56 ± 61.14	367.77 ± 54.69	7.10	<0.001
đ	0.326	0.000	0.004	I	I	I		
HADS-A	5.23 ± 1.16	5.05 ± 1.29	5.16 ± 1.75	4.91 ± 1.23	5.00 ± 1.16	5.12 ± 1.61	0.59	0.624
þ	0.335	0.761	0.512	I	I	I		
HADS-D	4.77 ± 1.61	$\textbf{4.86} \pm \textbf{1.25}$	4.70 ± 1.13	$\textbf{4.93} \pm \textbf{1.55}$	$\textbf{4.86} \pm \textbf{1.11}$	$\textbf{4.60} \pm \textbf{1.28}$	0.02	0.996
þ	0.827	0.927	0.961	I	I	I		
Values are mean ∃ SPPB, Short Physic Depression Scale.	Values are mean±standard deviation. SPPB, Short Physical Performance Batt Depression Scale.	Values are mean ± standard deviation. SPPB, Short Physical Performance Battery; PCS, physical component summary; MCS, mental component summary; 6MWT, 6-minute walking test; HADS, Hospital Anxiety and Depression Scale.	ηponent summary; MC	S, mental component	summary; 6MWT, 6-m	inute walking test; HA	DS, Hospita	l Anxiety and

Table 2. Physical function and mental health measurements between the two groups at three time points.

Xinlan et al.

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Variables	Intervention group	Control group	$t(\chi^2)$	Þ	
Length of hospital stay (days)	$\textbf{6.20} \pm \textbf{1.07}$	$\textbf{8.16} \pm \textbf{1.13}$	8.30	< 0.00	
Readmission	5	8	0.90	0.344	
Death	3	7	1.91	0.167	

Table 3. Clinical outcome measurements in the two groups.

Values are mean \pm standard deviation or number.

	Table 4.	Logistic	regression	analysis fo	or predicting	the g	likelihood of mortality	1.
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							95% CI for OR		
	В	SE	Wald	df	Þ	OR	Lower	Upper	
Age	0.058	0.105	0.306	Ι	0.580	1.060	0.862	1.303	
Sex	0.513	0.780	0.433	I	0.511	1.671	0.362	7.714	
Type of heart valve	-0.699	0.777	0.809	I	0.368	0.497	0.108	2.280	
SPPB	-0.878	0.329	7.126	I	0.008	0.416	0.218	0.792	
PCS	-0.023	0.050	0.212	I	0.645	0.977	0.886	1.078	
6MWT	-0.002	0.007	0.132	Ι	0.716	0.998	0.984	1.011	

Cl, confidence interval; OR, odds ratio; SE, standard error; df, degrees of freedom; SPPB, Short Physical Performance Battery; PCS, physical component summary; 6MWT, 6-minute walking test.

measurements (SPPB, PCS, and 6MWT) after early cardiac rehabilitation were entered into the logistic model, which assessed their effects on readmission and mortality (Table 3).

A logistic model was also used to predict mortality ($\chi^2(6) = 12.62$, p = 0.049, Nagelkerke R² = 0.265). Among the independent variables included in the model, only the SPPB was significant predictor of mortality (B = 0.878, p = 0.008, OR = 0.416, 95% CI: 0.218–0.792; Table 4), and a higher physical function was associated with a higher survival rate in patients with heart valve surgery.

Discussion

We investigated the effectiveness of early cardiac rehabilitation on patients with heart valve surgery in the hospital setting. We found that early cardiac rehabilitation was effective in significantly increasing physical function in patients and this effect remained in the long-term. Furthermore, improved physical function was associated with a higher survival rate after heart valve surgery. These results suggest that early cardiac rehabilitation is an effective approach for improving clinical outcomes in patients with heart valve surgery.

Patients who have cardiac surgery performed are accompanied by prolonged physical inactivity associated with reduced functional capacity. Physical activity positively affects cardiorespiratory fitness and cardiovascular function.³² Our study showed that participation in early cardiac rehabilitation improved physical capacity, including daily activity, such as an increased walking distance. This finding is similar to that in previous studies using exercise-based cardiac rehabilitation after discharge.33,34 hospital These studies reported an improved physical performance after exercise training in patients who had heart valve surgery, regardless of the type of surgery or the preoperative risk. This finding suggests that cardiac rehabilitation is beneficial in patients with heart valve surgery for enhancing functional capacity because increased physical activity and fitness lead to additional improvement in the health status.³⁵

There is a temporal relationship between exercise-based cardiac rehabilitation and the long-term physical activity level. Previous studies showed a significant increase in the physical activity level (e.g., walking distance) in patients with heart valve surgery who participated in cardiac rehabilitation compared with nonparticipants at 3 months to 1 year after rehabilitation.^{15,36,37} Consistent with this finding, we observed a long-term effect of early cardiac rehabilitation on physical function at 6 months after hospital discharge. Several studies have shown that patients who have cardiac surgery and receive an exercise training program show significantly greater improvement in selfefficacy than those who have usual care,^{38,39} which is sustained after the intervention and hospital discharge. Therefore, a possible reason for this long-term effect is that an improvement in physical function and heart rate recovery may positively affect the self-efficacy of patients. This in turn increases their confidence in physical activity, which may affect long-term functional capacity, such as walking longer distances.

In addition, high rates of hospital readmission and mortality have been reported in patients with valve surgery.^{40,41} Physical activity is efficacious in decreasing mortality and readmission rates in patients with coronary heart disease.¹⁵ The association between the physical activity level and survival in patients with heart valve surgery in the long term has been studied. These studies showed significant survival benefits after exercise-based cardiac rehabilitation.^{42,43} The present study showed that early cardiac rehabilitation resulted in a long-term effect on survival in patients with heart valve surgery. Additionally, participation in early cardiac rehabilitation was associated with a significant reduction in mortality because early cardiac rehabilitation contributes to a positive recovery of physical function after the surgery and a reduced length of hospital stay. Physical function has a preventive effect on mortality because it positively affects low-density lipoprotein cholesterol levels and blood pressure regulation. Our results are in agreement with those from previous meta-analysis studies.44-46 These previous studies reported a benefit of cardiac rehabilitation for a reduction in mortality and hospitalization rates. However, physical function did not predict hospital readmission in the present study. The reason for this lack of finding could be because hospital readmission in this study was for single cardiac events or symptoms, which may not be related to physical function. Moreover, heart failure is the reason for many readmissions in patients with heart valve surgery.⁴¹

It should be noted that in our study, the mental health of patients was not improved by early cardiac rehabilitation. This result is in accordance with that in a previous study⁴⁷ because no psychological intervention was performed in patients in the present study. Psychological interventions (e.g., education, discussion, and emotional support) appear to be effective in treating psychological symptoms of coronary heart disease, resulting in small and moderate improvements in depression and anxiety.^{48–50} Future research should consider the combination of early cardiac rehabilitation and psychological intervention to promote psychological recovery in patients.

The present study has several limitations. First, we focused on an early cardiac rehabilitation program only in patients undergoing elective heart valve surgery. The effect of early rehabilitation in patients undergoing other cardiac vascular surgeries has shown good reliability and validity in previous studies,^{51,52} there is still a likelihood of overestimation for the physical activity level. Third, although we adjusted for confounders, including detailed demographical variables and intraoperative clinical characteristics, we cannot exclude the possibility that early rehabilitation was affected by other factors, such as postoperative complications.

In summary, early cardiac rehabilitation is associated with a marked improvement in physical function in patients with heart valve surgery and may promote long-term survival. Early cardiac rehabilitation in the hospital could be an effective approach to improve the functional capacity and clinical outcomes for surgical patients.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Author contributions

Zhang Xinlan and Zheng Xiaoyan designed the study and submitted the manuscript. Wei Xue collected and analyzed data. Zhang Xinlan drafted the article. Zheng Xiaoyan and Wei Xue supervised this study. All authors read the final version of the manuscript and approved it for publication.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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