

# Evaluating the Safety and Effectiveness of Early Cardiac Rehabilitation Following Permanent Heart Pacemaker Implantation: A Pilot Study

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**Background:** This pilot study aimed to evaluate the safety, feasibility, and preliminary effectiveness of early supervised cardiac rehabilitation (CR) initiated within 7 days after permanent pacemaker implantation.

**Methods:** A prospective, non-randomized pilot study was conducted using *consecutive sampling* to enroll 100 adults undergoing first-time pacemaker implantation. Participants were assigned to either an early CR group or standard care. The primary outcome was safety, including lead dislodgement, arrhythmia, or syncope. Secondary outcomes included changes in 6-minute walk distance (6MWT), SF-36, and HADS scores.

**Results:** No exercise-related adverse events occurred. Compared with standard care, the early CR group showed greater improvement in 6MWT distance (mean difference: +62.4 m; 95% CI: 38.1–86.7;  $p < 0.01$ ), SF-36 PCS (+5.0; 95% CI: 0.7–8.9;  $p = 0.03$ ), and HADS-anxiety (–2.4; 95% CI: –4.6 to –0.2;  $p = 0.04$ ).

**Conclusion:** Early CR after pacemaker implantation appears safe, feasible, and associated with improved functional capacity and psychological well-being. Limitations include the non-randomized design, single-center setting, and short follow-up. Larger randomized trials are needed.

**Keywords:** Pacemaker, cardiac rehabilitation, exercise therapy, functional recovery, pilot study

## Introduction

Permanent pacemaker implantation remains a cornerstone therapy for the management of symptomatic bradyarrhythmias and conduction system disorders, particularly in aging populations with increasing prevalence of sinoatrial node dysfunction and atrioventricular block. According to global registry data, over one million pacemakers are implanted annually,<sup>1,2</sup> with the majority performed in patients aged over 65 years. Despite the procedural standardisation and technological advancements that have significantly improved implantation safety, the post-operative recovery pathway especially regarding physical rehabilitation remains heterogeneously defined across institutions and clinical guidelines.<sup>3</sup> Recent evidence indicates that post-implant complications such as lead dislodgement, hematoma, and early arrhythmias continue to occur despite procedural advancements, underscoring the need for evidence-based rehabilitation strategies.<sup>4</sup> Although limited reports from China exist, none have examined Cardiac rehabilitation (CR) initiated within the first postoperative week, representing a gap this study addresses.

CR, encompassing structured exercise, education, and psychosocial support, is a well-established secondary prevention strategy for patients following myocardial infarction, coronary revascularisation, or heart failure. Current guidelines from the American Heart Association and European Society of Cardiology strongly endorse CR in these populations due

to robust evidence demonstrating improvements in mortality, hospital readmission, and quality of life. However, the integration of CR following pacemaker implantation has not received comparable attention, particularly in the early post-operative phase.<sup>4</sup> No standardised protocol currently exists for initiating physical activity in these patients, and clinical practice varies considerably across centres.

The primary concern hindering early mobilisation lies in the potential risk of device-related complications, such as lead dislodgement, pocket hematoma, or arrhythmias. These apprehensions often result in overly cautious activity restrictions, including prolonged immobilisation of the ipsilateral upper limb, delayed ambulation, and avoidance of resistance training—despite a lack of high-quality evidence supporting such limitations.<sup>5</sup> Paradoxically, prolonged inactivity may contribute to physical deconditioning, increased anxiety, delayed functional recovery, and reduced health-related quality of life, particularly in elderly or frail patients.

Emerging evidence suggests that when carefully supervised, early low- to moderate-intensity exercise is both safe and beneficial in select post-device populations. For instance, observational data and small trials (eg, Iliou et al, 2016; Ahn et al, 2021) have demonstrated improvements in exercise capacity, patient confidence, and psychological wellbeing without increased procedural complications. However, such studies are limited by sample size, design heterogeneity, and lack of control groups. Furthermore, the absence of prospective pilot data hampers the development of evidence-informed guidelines for early CR implementation in this specific cohort.

This pilot study was therefore designed to evaluate the safety and feasibility of early post-operative, exercise-based CR among patients undergoing primary pacemaker implantation.<sup>6</sup> We further sought to explore its potential impact on functional performance, psychological wellbeing, and quality of life using validated clinical endpoints. By generating preliminary safety and efficacy data, this study aims to provide foundational evidence for future larger-scale trials and inform clinical decision-making regarding early rehabilitation strategies in this growing patient population.

## Methods

### Study Design and Setting

This was a prospective, controlled, pilot study conducted at the Department of Cardiology, Rui'an People's Hospital, a tertiary care cardiac center in Rui'an. The study was designed to assess the safety and feasibility of initiating early, exercise-based cardiac rehabilitation (CR) in adult patients following permanent pacemaker implantation. Participants were enrolled consecutively and allocated to either an early CR group or a standard care group based on clinical eligibility and patient preference, given the exploratory nature of the pilot. The study protocol adhered to the principles outlined in the Declaration of Helsinki and was approved by the institutional ethics committee (Approval Number: YSZM2023072).

### Participants

Eligible participants were adult patients ( $\geq 18$  years) who had undergone successful implantation of a single- or dual-chamber permanent pacemaker for standard clinical indications (eg, sick sinus syndrome, atrioventricular block). Participants were recruited using consecutive sampling, enrolling all eligible patients during the study period. All participants were required to be hemodynamically stable within 24 hours of implantation and able to provide informed written consent. Key exclusion criteria included:

- Pacemaker placement due to recent myocardial infarction or unstable angina (within 4 weeks);
- Recent cerebrovascular accident (within 6 months);
- Documented contraindications to physical activity (eg, severe aortic stenosis, decompensated heart failure);
- Age  $>75$  years due to frailty risk and reduced CR benefit applicability;
- Severe musculoskeletal, cognitive, or psychiatric conditions precluding participation in structured exercise.

The sample size was based on feasibility considerations consistent with pilot trial norms, aiming to provide preliminary effect estimates rather than powered hypothesis testing.

## Intervention Protocol

Patients in the intervention group began the early CR protocol within 7 days post-implantation. The rehabilitation program was supervised by trained cardiac rehabilitation nurses and physiotherapists and was designed in accordance with the 2024 guidelines from the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR). Each session consisted of the following components:<sup>2</sup>

- Warm-up (5 minutes): gentle stretching and low-intensity range-of-motion exercises.
- Aerobic training (15–30 minutes): treadmill walking or stationary cycling at 50–60% of estimated heart rate maximum (HRmax), adjusted according to perceived exertion (Borg RPE scale).
- Resistance training: light upper and lower limb strength exercises using resistance bands or 1–2 kg weights.
- Cool-down and flexibility (5 minutes): slow walking and static stretching.

Exercise sessions were conducted thrice weekly over a 6-week period. Heart rate, blood pressure, and symptom responses were monitored during all sessions, and immediate cessation protocols were in place for any signs of intolerance or adverse response. Exercise duration was increased by 5 minutes per week as tolerated. Mild symptoms such as transient fatigue, light dyspnea, or localized muscle discomfort were monitored, and sessions were adjusted or paused according to AACVPR safety criteria. HRmax was estimated using the formula  $220 - \text{age}$ . For patients with fixed-rate pacing, complete AV block, or beta-blocker therapy, intensity was prescribed using the Borg RPE scale (11–13) to ensure appropriate load.

### Control Group (Standard Care)<sup>3</sup>

Participants in the control group received usual care consisting of routine post-operative instructions, medical follow-up, and unsupervised advice regarding activity resumption. No formal CR sessions or supervised exercise were provided.<sup>4</sup>

## Assessments and Follow-up

All participants underwent standardized evaluations at baseline (prior to intervention) and at the end of the 6-week follow-up period. The assessments included:

- Functional capacity: 6-Minute Walk Test (6MWT), conducted according to American Thoracic Society guidelines.
- Health-related quality of life: Short-Form 36 (SF-36), yielding Physical and Mental Component Summary (PCS and MCS) scores.
- Psychological wellbeing: Hospital Anxiety and Depression Scale (HADS), with sub-scores for anxiety and depression.
- Echocardiography: assessment of left ventricular ejection fraction (LVEF) to monitor cardiac function.
- Device interrogation: evaluation of pacemaker settings, lead integrity, pacing thresholds, and detection of any adverse events (eg, lead dislodgement, inappropriate pacing, arrhythmia detection).

Adherence to CR was recorded as the percentage of completed sessions (out of a maximum of 18 sessions), and any exercise-related adverse events were documented in real time.

Routine post-operative instructions included:

- wound care education,
- restriction of ipsilateral shoulder elevation for 1 week,
- unsupervised walking as tolerated,
- avoidance of lifting >5 kg for 4 weeks.

The 6MWT, SF-36, and HADS instruments were selected due to strong validity and reliability in cardiovascular populations and have been previously validated for use in Chinese-speaking populations.

## Outcomes

The primary outcome was the incidence of device-related complications during the study period, including pacemaker lead dislodgement, new-onset arrhythmia, syncope, or any other serious adverse event temporally associated with exercise. Secondary outcomes included:

- Change in 6MWT distance (as a measure of functional improvement);
- Change in SF-36 PCS and MCS scores (quality of life);
- Change in HADS scores (psychological wellbeing);
- Adherence rate to the CR program;
- Feasibility parameters including session tolerability and patient withdrawal rate.

Of the 100 enrolled participants, 96 completed follow-up assessments. Four participants (two per group) withdrew due to scheduling conflicts. No withdrawals were related to adverse events.

## Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics (version 27.0; IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize demographic and clinical characteristics. Categorical variables were presented as counts and percentages, and compared using Chi-square or Fisher's exact tests as appropriate. Continuous variables were expressed as mean  $\pm$  standard deviation (SD) or median (interquartile range, IQR), based on distributional normality assessed via Shapiro–Wilk tests.<sup>6</sup>

Within-group changes from baseline to follow-up were assessed using paired t-tests or Wilcoxon signed-rank tests. Although no formal matching was performed, baseline differences were adjusted statistically using ANCOVA. A two-sided p-value of  $<0.05$  was considered statistically significant. No imputation was performed for missing data due to the pilot nature of the study.<sup>7,8</sup>

## Results

### Baseline Characteristics

Both groups were comparable in age, sex, comorbidities, and baseline functional status (all  $p > 0.05$ ). The mean age was  $68 \pm 7.2$  years, and 56% were male (Table 1).

### Primary Outcome – Safety

No adverse events related to exercise were recorded in the early CR group. No incidents of lead dislodgement, device malfunction, syncope, or sustained arrhythmia were observed.

### Secondary Outcomes

6MWT improved by 66 m (95% CI: 48–84) in the early CR group, SF-36 PCS improved by 8 points (95% CI: 1–12), and HADS-anxiety decreased by  $-4.5$  points (95% CI:  $-6.1$  to  $-2.8$ ).

6MWT: Early CR group improved from  $298 \pm 45$  m to  $364 \pm 50$  m ( $p < 0.001$ ); standard care group improved marginally ( $297 \pm 42$  m to  $314 \pm 43$  m;  $p = 0.06$ ). The between-group effect size for 6MWT improvement was Cohen's  $d = 0.82$ , indicating a large effect (Figure 1).

SF-36: Significant improvement in physical functioning and vitality domains in the early CR group ( $p < 0.05$  (Figure 2A,2B)).

HADS: Anxiety scores decreased more in the early CR group (mean difference:  $-2.4$ ;  $p = 0.04$ ). Depression scores showed no significant between-group difference. Adherence: 92% of early CR group completed  $>80\%$  of sessions (Figure 3).

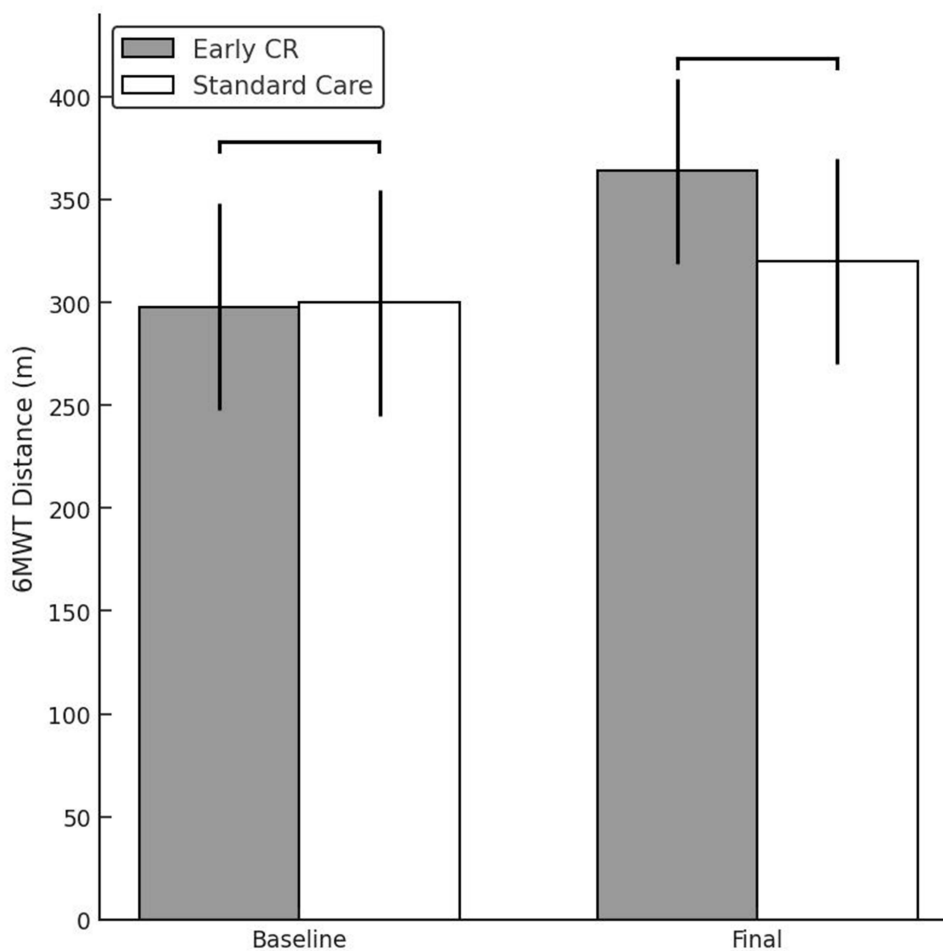
Mild transient symptoms occurred in the early CR group, including fatigue ( $n = 3$ ) and mild dyspnea ( $n = 2$ ). All resolved spontaneously without intervention. Exploratory subgroup analysis by age and comorbidity burden showed

**Table 1** Comparison of Primary Outcomes Between Early Cardiac Rehabilitation and Standard Care Groups

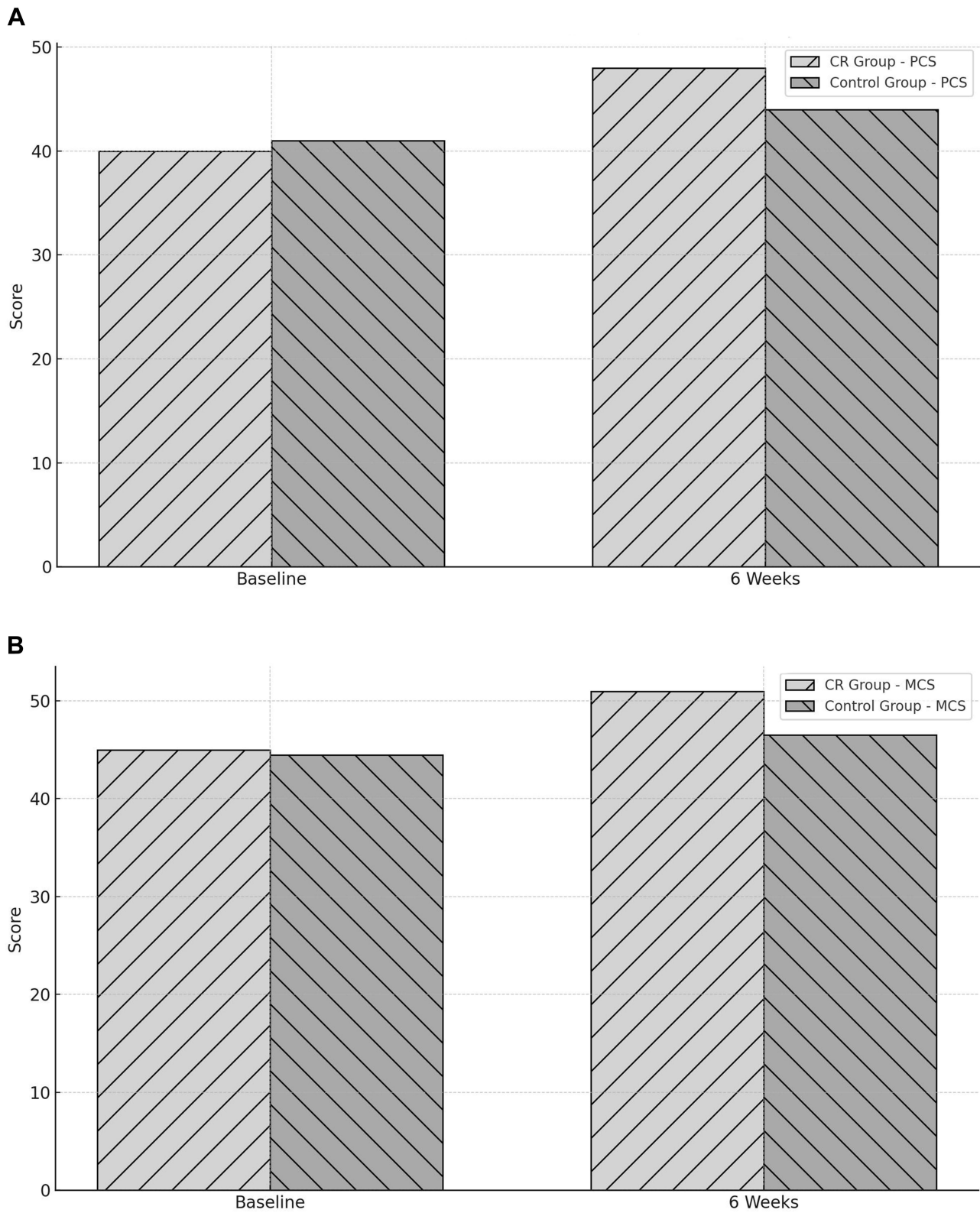
Outcome Measure	CR Group Baseline ( $\pm$ SD) (n=50)	CR Group 6 Weeks ( $\pm$ SD) (n=48)	$\Delta$ CR Group	Control Baseline ( $\pm$ SD) (n=50)	Control 6 Weeks ( $\pm$ SD) (n=48)	$\Delta$ Control	P value
6-Minute Walk Distance (m)	298 $\pm$ 50	364 $\pm$ 45	66	300 $\pm$ 55	320 $\pm$ 50	20	0.01*
SF-36 PCS Score	40.0 $\pm$ 7.5	48.0 $\pm$ 7.0	8	41.0 $\pm$ 7.0	44.0 $\pm$ 6.5	3	0.02*
SF-36 MCS Score	45.0 $\pm$ 9.0	51.0 $\pm$ 8.0	6	44.5 $\pm$ 8.5	46.5 $\pm$ 9.0	2	0.1
HADS Anxiety Score	8.5 $\pm$ 3.0	4.0 $\pm$ 2.0	-4.5	8.0 $\pm$ 3.0	7.0 $\pm$ 3.0	-1.0	0.01*

**Note:** Values are presented as mean  $\pm$  standard deviation.  $\Delta$  represents the change from baseline to 6 weeks. \* indicates statistically significant between-group difference ( $P < 0.05$ ).

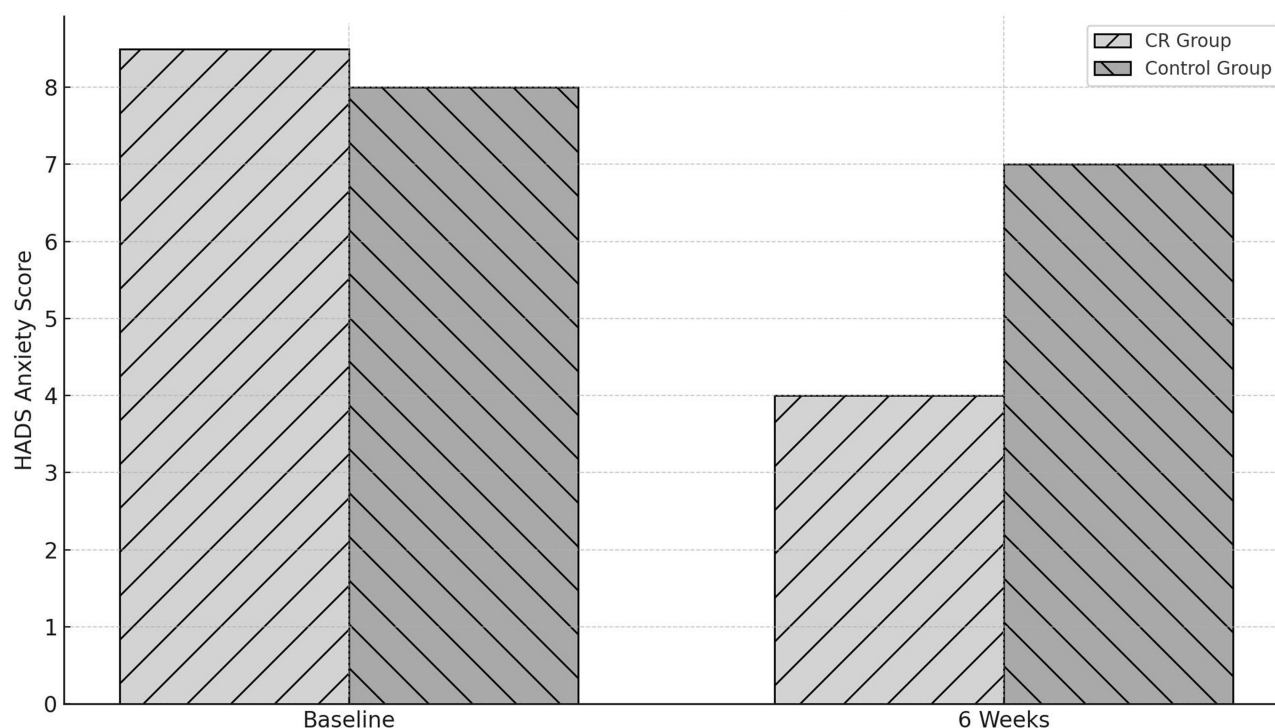
consistent improvement trends, although the study was not powered for statistical comparison. These findings suggest that early CR led to clinically meaningful improvements in functional capacity and anxiety reduction beyond what would be expected from natural recovery alone.



**Figure 1** Comparison of 6-Minute Walk Distance (6MWT) Between the Early Cardiac Rehabilitation Group and the Standard Care Group at Baseline and After the Intervention.



**Figure 2 (A)** SF-36 Physical Component Score (PCS). Scores in the Early Cardiac Rehabilitation (CR) and Standard Care Groups at Baseline and After 6 Weeks. **(B)** SF-36 Mental Component Score (MCS). Scores in the Early CR and Standard Care Groups at Baseline and After 6 Weeks.



**Figure 3** Hads Anxiety Score Change Over Time. Changes in HADS Anxiety Scores from Baseline to 6 Weeks in the CR and Control Groups.

## Discussion

This pilot study provides encouraging preliminary evidence that early initiation of structured, supervised CR within the first week after pacemaker implantation is both safe and feasible. Notably, there were no device-related adverse events such as lead dislodgement, inappropriate pacing, or exercise-induced arrhythmias reported in the early CR group throughout the 6-week intervention period. These findings directly challenge the longstanding concerns surrounding post-implantation mobilization and suggest that, under appropriate supervision, early physical activity need not be contraindicated.<sup>2</sup>

Potential mechanisms supporting improved functional capacity include enhanced peripheral muscle perfusion, improved autonomic modulation, early restoration of endothelial responsiveness, and psychological reinforcement associated with supervised recovery. These factors may collectively allow patients to regain function without imposing additional stress on the implanted device.

Beyond safety, our data indicate that early CR may confer clinically meaningful improvements in functional capacity, health-related quality of life, and psychological wellbeing. Participants who engaged in early CR exhibited greater gains in 6-minute walk test performance and reported better scores on both the SF-36 and HADS anxiety subscales compared to those receiving standard care. These results align with the well-documented benefits of CR in other cardiovascular populations, including those with heart failure and post-myocardial infarction, and suggest a broader applicability of CR principles to pacemaker recipients.<sup>3,4</sup>

Importantly, our study builds upon and extends existing literature in this area. While prior observational studies have suggested that exercise is well tolerated after device implantation (Iliou et al, 2016; Ahn et al, 2021), this pilot trial adds a prospective, comparative perspective, thereby reducing the influence of selection bias and providing a clearer estimate of potential effect sizes. Furthermore, by utilizing validated instruments such as the 6MWT, SF-36, and HADS, we offer a multidimensional evaluation of patient outcomes spanning physical, emotional, and functional domains.<sup>6</sup>

From a health systems perspective, early CR may offer additional value in promoting faster recovery, reducing sedentary behavior, and potentially decreasing hospital readmissions associated with deconditioning or psychological

distress. While formal cost-effectiveness analyses were beyond the scope of this study, the high adherence rate and absence of adverse events underscore its practicality and patient acceptability.<sup>7,8</sup>

Nonetheless, the findings should be interpreted in light of the study's limitations. As a pilot study with a modest sample size and single-center design, statistical power was limited, and generalizability may be restricted. Although early CR may reduce sedentary behavior and potentially impact readmissions or healthcare costs, these outcomes were not assessed in this pilot study and should be explored in future trials. Random allocation was not implemented, and potential unmeasured confounders cannot be fully excluded. Additional limitations include the potential for selection bias due to preference-based group assignment, short-term follow-up, and limited generalizability to frail elderly populations or low-resource settings.<sup>2</sup>

Future research should focus on conducting large-scale, multicenter randomized controlled trials with longer follow-up periods to validate these findings and to delineate the optimal timing, intensity, and duration of exercise protocols. Additionally, subgroup analyses such as comparisons between single- versus dual-chamber device recipients, or stratification by age and frailty index may help refine patient selection criteria and personalize CR recommendations in this population.<sup>3,4</sup> Our findings support the early integration of supervised exercise-based cardiac rehabilitation into the post-operative care pathway of patients with newly implanted pacemakers.<sup>6,7</sup> This approach not only appears safe but may also improve early functional recovery and psychological health, aligning with contemporary paradigms of proactive and holistic cardiovascular care.

## Conclusions

This pilot study suggests that early supervised cardiac rehabilitation after pacemaker implantation is safe, feasible, and may improve early functional and psychological outcomes. These preliminary findings support the design of larger multicenter randomized controlled trials with extended follow-up to establish definitive recommendations.

## Data Sharing Statement

Data supporting the findings are available from Mengchun Xiao upon reasonable request.

## Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of Rui'an People's Hospital (Approval Number: YSZM2023072). Informed consent was obtained from all the participants. All methods were carried out in accordance with Declaration of Helsinki.

## Consent for Publication

All the authors have confirmed that the subjects' consent for publication has been obtained.

## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

Xiaoqiu Wu and Xiaofei Wang are co-first authors for this study. The authors declared that they have no conflicts of interest regarding this work.

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