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Efficacy and safety of remote cardiac rehabilitation in the recovery phase of cardiovascular diseases (RecRCR study): A multicenter, nonrandomized, and interventional trial in Japan

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A B S T R A C T

Backgrounds: Remote cardiac rehabilitation has proven useful in patients with cardiovascular disease; however, the methodology had not been fully validated. This study aimed to investigate the efficacy and safety of remote cardiac rehabilitation (RCR) with real-time monitoring and an ergometer using a bidirectional communication tool during the recovery phase of cardiovascular diseases.
Methods: This multicenter, nonrandomized, interventional study was conducted at 29 institutions across Japan and enrolled patients with cardiovascular diseases who met indications for cardiac rehabilitation (CR) after receiving in-hospital treatment. The RCR group exercised at home using an ergometer and was monitored in real-time using interactive video and monitoring tools for 2–3 months. Educational instructions were provided concurrently through e-learning approaches. The safety of the RCR protocol and the improvement in peak oxygen consumption (VO2) were compared with those of the historical control group that participated in center-based CR.
Results: Fifty-three patients from the RCR group were compared with 103 historical controls having similar background characteristics. No patients in RCR experienced significant cardiovascular complications while engaging in exercise sessions. After 2–3 months of RCR, the peak VO2 improved significantly, and the increases in the RCR group did not exhibit any significant differences compared to those in the historical controls. During follow-up, the proportion of patients whose exercise capacity increased by 10% or more was also evaluated; this finding did not indicate a statistically significant distinction between the groups.
Conclusions: RCR during the recovery phase of cardiovascular diseases proved equally efficient and safe as center-based CR.

1. Introduction

Cardiac rehabilitation (CR), effective for patients with cardiovascular diseases, encompasses multidisciplinary interventions including exercise training, cardiovascular risk assessment, pharmacological education, nutritional counseling, and psychosocial support [1]. Several studies have demonstrated that CR improves exercise capacity or quality of life and reduces clinical outcomes such as hospitalization and mortality in patients with cardiovascular diseases [2–4]. However, unlike pharmacological therapy, CR exhibits a major limitation in terms of consistency, availability, and accessibility [4,5]. CR has a poor utilization rate, which can be attributed to multiple factors involving patients, healthcare providers, and social diversities [2,6–8]. It includes a low rate of patient referrals, patients' limited understanding of CR, or challenges in patient access to CR services. Moreover, the benefits of center-based rehabilitation are affected by multiple factors including exercise frequency [9]. Therefore, poor program adherence is a serious concern, which may significantly affect the achievement and beneficial effect of CR [8,10]. Furthermore, to minimize the risk of infection during the coronavirus disease 2019 pandemic, outpatient CR was reduced [11]. Consequently, adherence to outpatient CR therapy decreased.

To address the abovementioned issue, several reports have assessed home-based or remote cardiac rehabilitation (RCR), which is an alternative to outpatient center-based rehabilitation [12]. RCR involves multiple considerations, including monitoring during exercise training, medication-related patient education, nutritional counseling, and psychological support through a digital platform [13]. However, the current evidence on the safety and efficacy of RCR is limited. In contrast, CR methodologies and objectives exhibit minimal differences based on the phase (such as acute or maintenance phases). Nevertheless, CR during the recovery phase is comparatively important as a turning point in the subsequent clinical course. While undergoing CR during this period, patients should be guided during exercise using telemedicine to ensure safety. Real-time biological information monitoring is the most useful platform for ensuring patient safety during home-based exercise sessions. The current study examined the efficacy and safety of RCR with real-time monitoring using a bidirectional communication tool throughout the recovery phase of cardiovascular diseases. We conducted RCR research using a protocol comparable to center-based CR at facilities that were not accustomed to RCR.

2. Method

2.1. Study design

This prospective, multicenter, physician-initiated trial was performed to determine the efficacy and safety of RCR during the recovery phase of cardiovascular diseases. We enrolled patients from 29 facilities accredited by the Japanese Society of Cardiac Rehabilitation across Japan. The details of the trial design have been described in a previous study [14]. This study was conducted in accordance with ethical guidelines and the Declaration of Helsinki. This clinical trial was registered in the University Hospital Medical Information Network—Clinical Trials Registry (UMIN-CTR: UMIN000042942). In addition, the protocol was approved by the Institutional Review Board of Tokyo University Hospital (2020305NI).

2.2. Patient selection

The enrolled patients included men and women aged >20 years who were discharged after in-hospital treatment for cardiovascular diseases (including ischemic heart disease, heart failure, aortic disease, conditions requiring cardiac surgeries, and peripheral artery disease), which are indicated for CR. The patients underwent screening upon hospital admission and were enrolled during admission or immediately after discharge from the hospital. Patients' proficiency in operating electronic devices associated with RCR was also assessed. We selected participants who had cohabitants or had someone nearby who could assist them. The exclusion criteria were as follows: patients with contraindications to exercise due to complications (including severe valve disease, advanced heart failure based on the New York Heart Association [NYHA] Classification IV, life-threatening arrhythmias such as ventricular tachycardia, and severe renal or hepatic disease), and those with an implanted defibrillator or ventricular assist device. We also excluded patients who were unable to perform aerobic exercise on an upright ergometer or lacked knowledge of how to use the electronic device in this study.

2.3. Intervention

The RCR group used calibrated ergometers, and tablet devices for face-to-face communication during exercise and for e-learning guidance required for performing RCR after hospital discharge. Patients with RCR initiated an aerobic exercise session utilizing an ergometer after receiving exercise instructions and device setup. Throughout the

session, they were monitored by medical professionals via real-time video conversation using the provided device. The session lasted approximately 30–40 min, three times per week. The intensity was set individually using the anaerobic threshold, which was determined based on the heart rate or the cardiopulmonary exercise testing results. A Borg scale score of 11–13 was the target level. The intensity of exercise was determined in accordance with the Japanese guideline standard procedure used in center-based CR [14]. Before each exercise session, body temperature, weight, blood pressure, and heart rate were evaluated. A physiotherapist monitored the patients' condition during exercise by utilizing interactive video tools. Blood pressure, heart rate, and oxygen saturation were regularly monitored. In some patients, the electrocardiographic waveform was recorded. These multifaceted biometric data were transmitted to the physiotherapist stationed at the CR center, who oversaw the implementation of safe and effective exercises for the patients. Real-time monitoring was primarily conducted by physiotherapists and supervised by staff doctors to ensure safety. This RCR protocol differed from center-based CR in that it did not include resistance training. Moreover, during rehabilitation, video-based learning was conducted using a tablet device. The e-learning content included information regarding cardiovascular disease risk, nutrition, and lifestyle modification for disease control (supplementary material 1). The instructors selected various education kits for each session. If an issue was detected in the monitoring devices or transmission, the exercise session would be discontinued from a safety point of view, and adjustments would be made to resume the subsequent exercise session.

2.4. Control subjects

We retrospectively extracted the medical records of subjects in the control group who were discharged after in-hospital treatment for diseases indicated for CR from the same facilities. Another criterion for inclusion in the control group was the availability of data from the cardiopulmonary exercise test (CPET) or the 6-Minute Walk Test (6MWT) during admission and 2–3 months after discharge. The control group consisted of candidates selected for center-based CR; however, if participation in center-based CR was not feasible, the reasons for this were also determined. Center-based CR in the recovery phase was defined as participation in at least one CR session within 60 days of discharge. The institutions that participated in this study conducted CR in accordance with the Japanese Circulation Society's recommendations [15]. A standard CR program includes three 60-minute sessions per week, and typical exercise programs include warm-up exercises, both aerobic exercise and resistance training, as well as cool-down and stretching movements after each session. The exercise intensity was consistent with the RCR protocol. These were conducted under the direct supervision of an experienced medical staff member.

2.5. Clinical outcome

The primary outcome was the change in peak oxygen uptake between the initiation of RCR and 2–3 months following RCR.

The secondary outcome for efficacy is the ratio of exercise capacity improvement. Indeed, the CPET was not available in some facilities due to the coronavirus disease 2019 pandemic [16]. If peak VO_2 data was not available, we replaced it with oxygen uptake at the anaerobic threshold (AT) level or the 6MWT distance. Facilities that could perform CPET were not necessarily required to conduct a 6MWT evaluation. To evaluate changes in exercise capacity, the participants were classified based on exercise capacity improvement (10% or no improvement) according to each modality. The percentage of exercise capacity improvement was compared between RCR and control. In addition to exercise capacity parameters, the B-type natriuretic peptide levels and left ventricular ejection fraction (LVEF) on echocardiography were evaluated before and at the end of the study. During enrollment, data on the presence or absence of cohabitants was obtained.

In the safety analysis, we defined the following as severe adverse events during exercise training: chest pain or other cardiovascular symptoms for which the medical professionals recommended that the participants should be transferred to the hospital; severe ventricular arrhythmias; syncope; and cardiopulmonary arrest.

2.6. Statistical analysis

Patients for whom exercise capacity could be evaluated utilizing the same modality (CPET or 6MWT) at baseline and follow-up were selected. Cases in which the evaluation method for exercise capacity altered from baseline to follow-up were excluded.

Data from the RCR and historical control groups were expressed as mean (standard deviation) and median (quartiles). Categorical variables were presented as absolute numbers and percentages. Categorical and continuous variables were compared between patients who received RCR and those who underwent center-based CR. Continuous variables were analyzed using the two-tailed independent samples *t*-test and the Mann–Whitney *U* test for data with normal and non-normal distributions, respectively. For categorical variables, the chi-square test was used.

The paired *t*-test was used to compare data at baseline and follow-up. Analysis of covariance was used to compare changes in BNP, LVEF, and exercise capacity parameters at baseline and follow-up between patients with RCR and patients with center-based CR. In addition, we performed an inverse probability of treatment weighting (IPTW) analysis to adjust the baseline confounding variables. Inverse probability weights were derived from patient demographic characteristics, including age, sex, body mass index, and heart disease. A P value of <05 was considered statistically significant. Statistical analyses were performed using STATA software version 16 (StataCorp LP, College Station, TX, USA) or JMP software version 17 (SAS Institute, Cary, SC, USA).

3. Result

3.1. Characteristics of the patients

A total of 57 patients were enrolled and included in the RCR group from January 14, 2021, to March 31, 2021. Of the 57 patients, 1 withdrew from the clinical trial (reason: patient's refusal to continue the study due to the burden of exercise). Meanwhile, 127 patients were incorporated retrospectively as historical controls in the data collected from May 2015 to March 2021. Both groups included individuals who had data on exercise capacity at the beginning and end of the study. Among the historical controls, we excluded patients who could not participate in center-based CR ($N = 15$; reasons are presented in Fig. 1) and included only those who received center-based CR (Fig. 1). Finally, we compared the data of 53 patients with RCR and 103 historical controls.

Table 1 shows the characteristics of the participants. The two groups were similar in terms of age, body mass index, sex, and medications used. The cohort represented typical Japanese patients with cardiovascular disease including heart failure and ischemic heart disease.

3.2. Adverse events during exercise session

In the RCR group, 56 patients successfully completed the training program. Only one facility had past RCR experience; the others had limited experience. The duration of RCR was 77.8 ± 17.7 days. The mean number of sessions was 24.9 ± 8.4. No serious adverse events were reported in 830 patient-hours during or immediately after remote exercise training in RCR.

3.3. Changes in clinical parameters including exercise capacity

At baseline, the peak VO2 and VO2 at the AT level were comparable

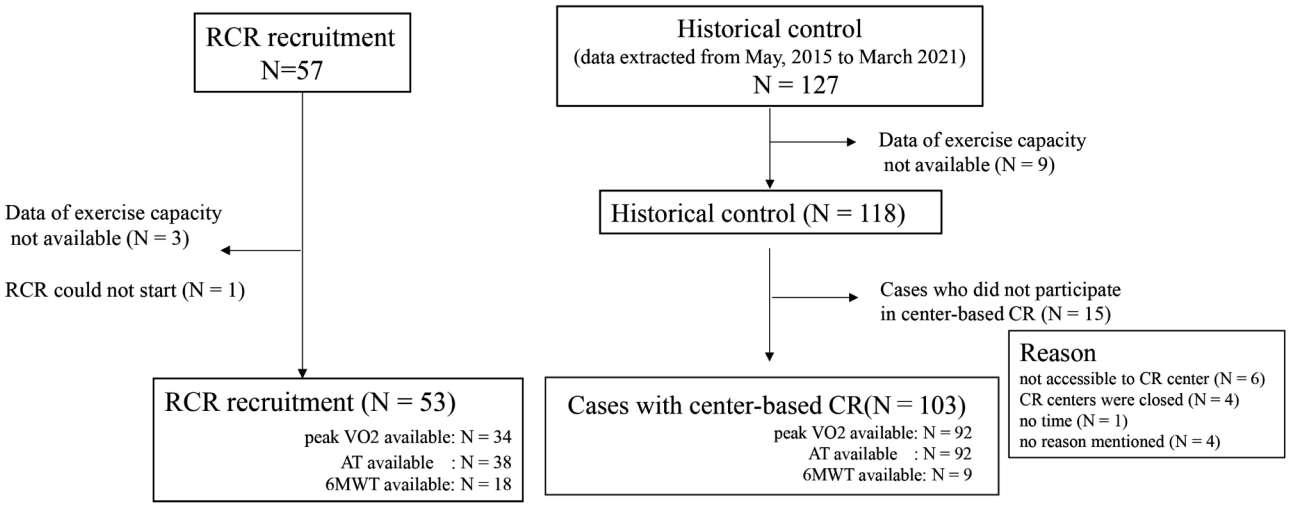

Fig. 1. Flow chart of the participants. RCR, remote cardiac rehabilitation; VO2, oxygen consumption; AT, anaerobic threshold; 6MWT, 6-Minute Walk Test, CR; cardiac rehabilitation.

between the RCR and historical control groups. Meanwhile, the RCR group exhibited a significantly higher 6MWT distance than the historical control group (Table 2a). Further, the RCR group demonstrated lower B-type natriuretic peptide levels and a higher LVEF than the historical control group. Hence, the RCR group might have had comparatively stable patients.

After the RCR sessions, follow-up examinations were performed (median: 97.5 [91–112] days later). The historical controls exhibited a similar duration of interval between the baseline and follow-up measurements of exercise capacity (median: 88 [74–112] days). In terms of exercise capacity, the peak VO2 based on CPET improved in the two groups (Table 2a). Further, the VO2 at the AT level and the 6MWT distance improved significantly in the two groups (Table 2a). The p-values in Table 2a demonstrated the lack of a significant difference in improvements between the two groups. Fig. 2 depicts the peak VO2 and VO2 at the AT level for each group in a box-and-whisker diagram.

The percentage of patients whose exercise capacity improved to >10% at follow-up was also evaluated (Table 2a and Supplementary Fig. 1). We observed these improvements in 57 (55.3%) patients in the historical control group and 23 (42.5%) patients in the RCR group. The results did not significantly differ between the historical control and RCR groups.

We performed an IPTW analysis, controlling for the baseline confounding variables. The absolute standardized mean differences of the covariates diminished and achieved effective balance after IPTW (Supplementary Fig. 2). Table 2b shows the result of IPTW, indicating no significant differences in peak VO2 and AT before and after rehabilitation between the two groups.

4. Discussion

In this study, improvements in exercise capacity were similar in patients undergoing RCR and those who underwent conventional center-based outpatient CR during the recovery phase of their cardiovascular disease. Our protocol comprised RCR with real-time monitoring using a bidirectional communication tool and e-learning education kits. The exercise protocol specified the use of a quality-controlled ergometer that was delivered to the patients' houses for aerobic exercise. There was no significant difference in terms of exercise tolerance improvement between patients undergoing center-based outpatient CR and those receiving RCR. Compared to conventional center-based outpatient CR, RCR might exhibit a marginally diminished impact. The relatively inadequate improvement in exercise capacity observed in RCR may be ascribed to the staff's lack of familiarity with the program or an unprepared system for RCR. In fact, remote communication issues were reported.

Several studies have investigated the efficacy of RCR [12]. Exercise training in RCR involves providing guidance for an appropriate exercise protocol for each patient and ensuring the safety and appropriateness of the exercise regimen. However, the procedures used for each RCR vary widely and must be evaluated according to the protocol. Home-based CR exercise protocols commonly include walking with varying degrees of assistance via telephone calls or in-home visits from medical professionals such as exercise therapists [13]. Some studies utilized monitoring to subsequently verify the adequacy of exercise training intensity. For example, in the study by Krral et al. (FIT@Home study), the RCR group was instructed about the intensity of exercise training [17]. Afterward, patients perform voluntary exercise and upload the data, which is reviewed by an exercise therapist. In contrast, Telerehab III, a study performed in Europe, aimed to present a remote approach to outpatient CR. Each patient wore an accelerometer, uploaded the data as appropriate on the web, and received regular guidance based on the data [18]. The study prescribed exercise in the form of walking. By not explicitly defining the exercise approach as described in the study, it can create more workout possibilities. However, the training effect may vary, leading to insufficient exercise effects.

Most studies used telephone counseling, SMS, email, etc. as a means of communication between patients and exercise therapists, as in Rawstorn's review [19]. By contrast, there were some that achieved exercise monitoring based on the timely confirmation of biometric information. A report from Australia revealed remote surveillance CR for patients with ischemic heart disease (REMOTE-CR) [20]. When outside the hospital, the patient wears a device for monitoring cardiac and respiratory rates, a one-lead ECG, and an accelerometer. Information is transmitted to the exercise therapist in real-time. The exercise therapist communicates exercise instructions to the patient through a voice transmission sent to the patient's earphone. Furthermore, there were also studies using devices that automatically regulate the intensity of exercise load [21]. The device contained a mechanism for adjusting the load amount by issuing an alarm when it was overloaded. In these various real-time monitoring methods, we adopted a method in which the operation of the exercise load is adjusted manually, while real-time monitoring is performed through video chat. Exercise therapists supervise patients during exercise sessions via real-time monitoring using electrocardiogram and intermittent blood pressure monitoring. They might observe the patient's physical condition while exercising and inquire about any symptoms, if necessary. Changes in the patient's condition can be monitored at an early stage with this real-time

Table 1
Baseline characteristics.

	Control n = 103	Remote CR n = 53	p-value
Background			
Age (year)	64.2 ± 13.5	63.1 ± 12.9	0.62
Gender male (%)	75(72.8)	40(75.5)	0.58
BMI (kg/m2)	23.5 ± 3.3	24.4 ± 4.0	0.17
Life Style, n (%)			
Living alone	20(19.4)	4(7.5)	0.11
Smoking, n (%) Past / Current	48(46.6)/15 (14.6)	23(43.3)/7 (13.2)	0.75
Clinical parameters			
Systolic BP (mmHg)	114.3 ± 14.9	117.2 ± 15.4	0.26
Diastolic BP (mmHg)	68.3 ± 11.0	68.1 ± 10.9	0.82
Heart rate (beat/minute)	71.5 ± 11.1	68.8 ± 10.5	0.15
Laboratory data			
Hb (g/dl),	13.0 ± 2.1	13.0 ± 1.9	0.84
Alb (mg/dl),	3.7 ± 0.5	3.8 ± 0.5	0.47
eGFR (mL/min/1.73 m^2)	63.5 ± 22.1	63.5 ± 21.4	0.99
HbA1c (%),	6.2 ± 0.8	6.1 ± 0.9	0.32
LDL (mg/dl),	100.2 ± 33.3	87.5 ± 30.5	0.021*
HDL (mg/dl),	42.4 ± 13.0	41.6 ± 12.6	0.72
Medical history, n (%)			
History of HF hospitalization, n (%)	23(22.3)	7(13.2)	0.33
Hypertension	72(70.0)	34(64.2)	0.57
Diabetes mellitus	40(38.8)	16(30.2)	0.32
Lipid disorders	54(52.4)	34(64.2)	0.12
Stroke	6(5.8)	0(0)	0.024*
Peripheral artery disease	5(4.9)	4(7.5)	0.48
COPD	5(4.9)	2(3.8)	0.76
PCI	42(40.8)	25(47.1)	0.39
CABG	9(8.7)	3(5.7)	0.51
Heart surgery	12(11.6)	4(7.4)	0.43
Drugs, n (%)			
Beta blockers	73(70.9)	37(69.8)	0.97
ACE-i/ARB	66(64.1)	26(49.1)	0.09
Loop diuretics	47(45.6)	21(39.6)	0.53
Indication for CR			
Ischemic heart disease	49(47.8)	23(43.4)	0.13
heart failure	36(35.0)	20(37.7)	
post cardiac surgery	14(13.6)	4((7.5)	
aortic disease	4(3.9)	6(11.3)	

Abbreviation: BMI; body mass index, HF; heart failure, CR; cardiac rehabilitation, BP; blood pressure, Hb; hemoglobin, Alb; albumin, eGFR; estimated glomerular filtration rate, LDL; low density lipoprotein, HDL; high density lipoprotein, COPD; chronic obstructive pulmonary disease, PCI; percutaneous coronary intervention, CABG; coronary artery bypass grafting, ACEi; angiotensin converting enzyme inhibitor, ARB; angiotensin II receptor blocker, ARNI; Angiotensin receptor/neprilysin inhibitor, SGLT2; sodium-glucose co-transporter inhibitor.

monitoring method. Since it is not possible to take immediate medical treatment, it is considered inferior in terms of safety compared with outpatient CR. However, the assurance of safety is comparatively high in RCR [22] because concise changes during exercise can be checked immediately through real-time monitoring. Moreover, the exercise intensity can be quickly and dependably modified.

Regarding safety concerns, we ensured that a caregiver would be able to respond to any exercise-related event. No serious adverse event was detected during 830 patient-hours exercise sessions. In fact, in one systematic review about the safety of home-based CR, the incidence rate of severe adverse events was one per 23,823 patient-hour [23]. Although the risk of an adverse event is extremely low during exercise training, RCR should not be prescribed to high-risk patients.

There exist multiple distinctions between home-based RCR systems that do not incorporate real-time monitoring and those that do. Home-based RCR without real-time monitoring has several advantages in terms of giving patients more opportunities for exercise training. It has minimal scheduling barriers, potentially increasing the frequency of exercise sessions [24]. Moreover, its implementation as a precursor to telemedicine devices is simplified. Real-time RCR monitoring, on the other hand, enhances exercise session safety. A general inverse association exists between convenience and safety in RCR; therefore, disease severity, the safety of exercise, and the social situation of the patient must be considered when selecting the form of RCR.

The current study also incorporated patient educational support through an e-learning kit. This intervention might be effective in improving adherence and preventing secondary events via diet and lifestyle management. However, it is challenging to evaluate its contribution to improving exercise tolerance within a short time [25]. Further in-depth examination of the multifaceted effects of CR is required in the future. As observed during the implementation of RCR, information technology (IT) literacy is another important issue in RCR [26]. Indeed, patient IT literacy is indispensable for the efficient advancement of RCR [27]. In this study, patients were selected after considering IT literacy to some extent, which led to selection bias. We checked IT literacy by asking directly whether participants were able to operate new electronic devices. There was no actual preparation test for it. However, for the accurate evaluation of IT literacy, it would be very helpful to have an intelligence test that is related to the ability to operate an electronic device. In a broader sense, accessibility to remote health devices also has a substantial impact on RCR [28]. The current results might be based on such selection bias; therefore, it is important to consider whether these results can be generalized to all patients in a future study involving a larger cohort of individuals with diverse intellectual abilities. The impact of technological literacy on the effects of remote medicine should be investigated more precisely in future studies. A recent publication in Australia's clinical guide for CR stated that it is important to validate both the safety of the location where patients exercise remotely and their IT literacy [29]. There is also a strong need for guidelines that emphasize safety when proceeding with RCR.

In this study, the RCR cost would encompass the cost of the devices, which are installed in the patient's home (ergometer, two types of tablets [one for face-to-face communication during exercise and another for e-learning guidance], and biological monitors), transportation cost of the device, and equipment cost to the RCR facility (for monitoring and an ergometer for patient guidance). Communication issues throughout the RCR also resulted in management expenses. On the other hand, it is expected that costs from hospital visits could be reduced. However, data for accurately calculating cost-effectiveness was not available in this study.

The value of baseline exercise capacity might relate to the applicability of the results of this study. Historical controls in this study exhibited a lower baseline exercise capacity than that shown in several previous studies [17,20,30], whereas there were similar reports of equivocal baseline exercise capacity [31,32]. A bias toward more severe cases of historical controls may exist through the selection of cases in which exercise capacity was examined relatively frequently. Nonetheless, no data was available on the dropout rate among historical controls, which may have introduced some biases. The historical controls exhibited improvement percentages of 11.7% for peak VO2, 12.2% for VO2 at AT, and 32.0% for 6MWT distance with respect to CR improvement. In contrast, our study recorded improvement percentages of 9.3% for peak VO2, 9.5% for VO2 at AT, and 10.3% for 6MWT distance. These improvement percentages were equivocal with previous studies [20,33–36].

In recent years, research on RCR has further increased; however, a standardized form that can be implemented at multiple institutions has

Table 2a
Primary and secondary outcomes, change in exercise capacity and other parameters in BNP, LVEF.

	Control (N = 103)			**RCR** (N = 53)			
	Baseline	Follow-up	Within group p-value	Baseline	Follow-up	Within group p-value	Between groups p-value
BNP (pg/dl)	160.3 [79–357] (N = 57)	81.1 [33–201] (N = 57)	<0.001	58.5 [26–189]** (N = 30)	24.2 [8–92] (N = 30)	<0.001	0.27
LVEF (%)	46.2 ± 18.0 (N = 70)	53.1 ± 15.4 (N = 70)	<0.001	56.2 ± 18.0* (N = 45)	58.5 ± 13.2 (N = 45)	0.12	0.68
6MWT (m)	372.5 ± 165.7 (N = 9)	491.8 ± 151.2 (N = 9)	<0.001	434.3 ± 105.4* (N = 18)	479.8 ± 125.4 (N = 18)	0.092	0.13
AT (ml/min/kg)	10.6 ± 2.7 (N = 92)	11.9 ± 3.0 (N = 92)	<0.001	10.5 ± 1.7 (N = 38)	11.5 ± 2.3 (N = 38)	0.0024	0.40
Peak VO2 (ml/min/kg)	15.4 ± 4.4 (N = 92)	17.5 ± 5.0 (N = 92)	<0.001	16.1 ± 4.1 (N = 34)	17.6 ± 5.0 (N = 34)	0.020	0.50
Composite endpoint		57(55.3)			23 (42.5)		0.18

** p < 0.01, * p < 0.05 as compared with control.
RCR; remote cardiac rehabilitation, BNP; B-type natriuretic peptide, LVEF; left ventricular ejection fraction, 6MWT; 6-minute walk test, AT; anaerobic threshold, VO2; oxygen consumption.

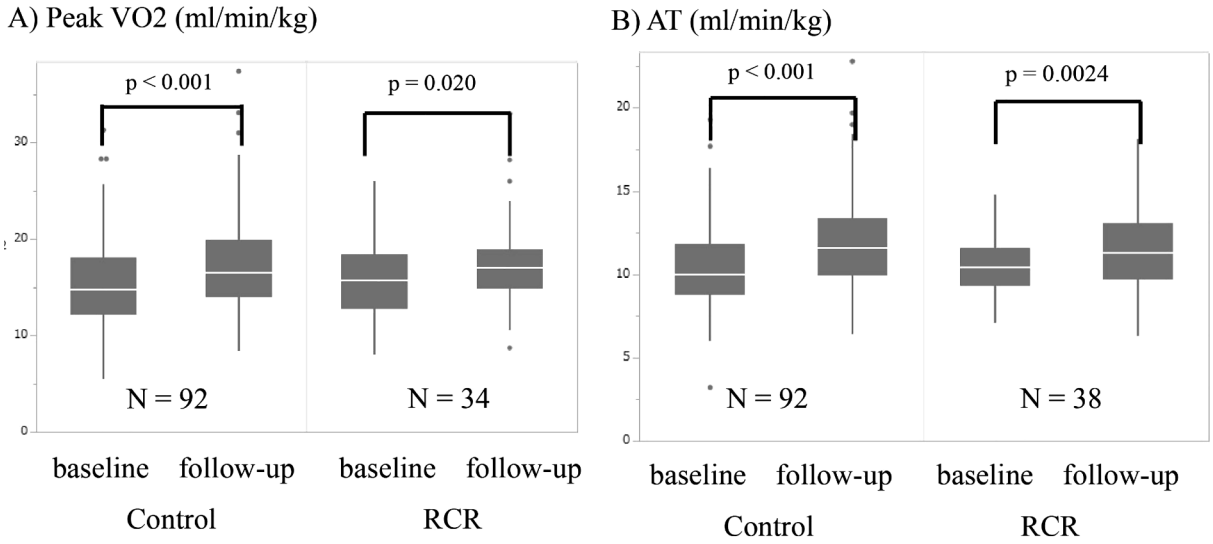

Fig. 2. Changes in exercise capacities at baseline and follow-up in patients receiving RCR and those who were historical controls. VO2, oxygen consumption; AT, anaerobic threshold; RCR, remote cardiac rehabilitation.

Table 2b
Estimated difference between RCR and control groups using inverse probability of treatment weighting.

		estimated difference	p-value
AT	Baseline	0.07 (−0.73–0.87)	0.86
	Follow up	−0.43 (−1.36–0.50)	0.47
	Difference	−0.38 (−1.13–0.37)	0.38
Peak VO2	Baseline	0.55 (−1.05–2.14)	0.68
	Follow up	−0.29 (−2.04–1.46)	0.74
	Difference	−0.84 (−2.15–0.48)	0.21

The result of linear regression analysis employing inverse probability of treatment weighting. In terms of AT values, 38 cases were included in the RCR group, and 87 cases in the control group. For Peak VO2 values, 34 cases were included in the RCR group, and 87 cases in the control group.
RCR; remote cardiac rehabilitation, AT; anaerobic threshold, VO2; oxygen consumption.

not yet been fully established. We conducted RCR research using a protocol similar to center-based exercise therapy to facilitate the introduction of RCR to instructors who were unfamiliar with it. Future requirements will include the establishment of RCR-related guidelines and an expert education system to support the various forms of RCR. This study's novel finding was that the efficacy and safety of RCR had been validated in patients in the recovery phase. Our study targeted patients in the recovery phase, including many patients who had recently been discharged from the hospital. To increase safety, RCR was adopted utilizing real-time monitoring to target individuals who were at higher risk than in earlier studies. Because we prioritized efficacy and safety in this study, we were not able to reduce the burden on medical professionals. However, if we create a system that improves the efficacy of supervision for participants, it would be possible to solve the issue.

Consequently, in this study the burden on medical professionals for real-time monitoring increased. Since the present scheme is an RCR that is close to a center-based type, we can expect a long-term course similar to that of a center-based CR, but actual confirmation of the long-term prognosis is warranted in the future.

5. Study limitation

The current study has several limitations. First, the effect of exercise tolerance was evaluated for a short period of time. Thus, the long-term impact of clinical events should be established. In addition, as historical controls, we selected participants for whom exercise capacity could be evaluated for a duration of 2–3 months. As a result, historical controls

might have a trend toward high adherence, which may give rise to some biases. Another limitation was that controls, who underwent center-based CR, were not simultaneously recruited with the participants undergoing RCR. However, many CR programs involving patients with cardiovascular disease who were most at risk were suspended during the study period because of the coronavirus disease 2019 pandemic, which limited human contact [37,38]. Furthermore, we lacked data regarding the frequency of exercise sessions in center-based CR for the control group. The study sample size was comparatively limited, potentially introducing a type 2 error risk. The evaluation method for exercise capacity could not be unified in this study because there were some facilities where CPET is not conducted due to the coronavirus disease 2019 pandemic [39]. We could not unify the analyses of CPET results either. We recruited study participants similar to that in center-based settings, considering the inclusion criteria. However, the efficacy of RCR for patients with each cardiovascular disease, such as ischemic heart disease or heart failure, should be investigated individually in the next stage. In addition, the improvement of the exercise capacity in the recovery phase may have occurred naturally in most cases without exercise intervention. Therefore, the efficacy of RCR should be verified in a more robust way using randomized studies in the future. This study aimed to implement RCR in as many facilities as possible. The protocol employed was according to center-based CR; thus, it seemed easy to use even in facilities that were unfamiliar with RCR. By contrast, the efficiency might be decreased, and the number of participants could not be easily increased due to the protocol. However, it would be feasible for several facilities across extensive areas to implement RCR, as indicated in this research. Either way, based on the verification of the efficacy of this RCR protocol, our results were insufficient. Indeed, it remains to be determined whether this exhibits an effect on improving prognosis and whether this method can be disseminated to improve overall CR participation. Conducting studies such as randomized control trials or comparison studies using large numbers of controls is warranted.

6. Conclusion

RCR in the recovery phase of cardiovascular disease was found to be adequately efficient and safe when compared to center-based outpatient CR.

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Author contribution

H Itoh, E Amiya, T Hasegawa, S Makita and Y Kimura contributed to the conception and design of the work. MS, KN, MT, TK, TY, YK, HO, MS. HY, KM, SF, SM, TT, AD, YK, TK, KH, HA, TN, YU, HS, DK, KK, HS, TO, RT, SU, SS, MK, HS, MNY, TO, YI. were responsible for the acquisition of data. H Itoh, E Amiya and T Jimba performed all data analyses. H Itoh and E Amiya drafted the manuscript. K Issei, T Hasegawa and Y Kimura critically reviewed the manuscript. All the authors gave comments and revised the manuscript. All the authors approved the final version to be submitted.

CRediT authorship contribution statement

Hidetaka Itoh: Writing – original draft, Investigation, Data curation, Conceptualization. **Eisuke Amiya:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Formal analysis, Data curation, Conceptualization. **Takahiro Jimba:** Supervision, Formal analysis. **Mai Shimbo:** Supervision, Data curation. **Koichi Narita:** Investigation. **Masanobu Taya:** Investigation. **Toshiaki Kadokami:** Investigation. **Takanori Yasu:** Investigation. **Hideki Oka:** Investigation. **Masakazu Sogawa:** Investigation. **Hiroyoshi Yokoi:** Investigation. **Kazuo Mizutani:** Investigation. **Shin-ichiro Miura:** Investigation. **Tatsuo Tokeshi:** Investigation. **Ayumi Date:** Investigation. **Takahisa Noma:** Investigation. **Daisuke Kutsuzawa:** Investigation. **Soichiro Usui:** Investigation. **Shigeo Sugawara:** Investigation. **Masanori Kanazawa:** Investigation. **Hisakuni Sekino:** Investigation. **Miho Nishitani Yokoyama:** Investigation. **Takahiro Okumura:** Supervision, Formal analysis. **Yusuke Ugata:** Investigation. **Shinichiro Fujishima:** Investigation. **Kagami Hirabayashi:** Investigation. **Yuta Ishizaki:** Investigation. **Koichiro Kuwahara:** Investigation. **Yuko Kaji:** Investigation. **Hiroki Shimizu:** Investigation. **Teruyuki Koyama:** Investigation. **Hitoshi Adachi:** Investigation. **Yoko Kurumatani:** Investigation. **Ryoji Taniguchi:** Investigation. **Katsuhiko Ohori:** Investigation. **Hirokazu Shiraishi:** Investigation. **Takashi Hasegawa:** Supervision. **Shigeru Makita:** Supervision. **Issei Komuro:** Supervision. **Yutaka Kimura:** Supervision, Investigation.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Eisuke Amiya belongs to the Department, endowed by NIPRO-Corp, Terumo-Corp., Senko-Medical-Instrument-Mfg., Century-Medical, Inc., ONO-pharmaceutical-Co., Ltd. Medtronic-JAPAN Co., Ltd, Nippon-Shinyaku Co., Ltd, Mochida Pharmaceutical Co.; Boehringer Ingelheim Pharmaceuticals Inc., Abiomed-Inc, AQuA-Inc, Fukuda-Denshi Co., Ltd, and Sun-Medical-Technology-Research Corp. Eisuke Amiya received research funding from Bristol-Myers Squibb Co. The authors declare that the research was conducted in the absence of commercial or financial relationships that could be construed as potential conflicts of interest.

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Appendix A. Supplementary data

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