



Can Karate be a Safe and Effective Activity during a Cardiac Rehabilitation in Patients with Heart Failure and Reduced Ejection Fraction? The Karead Protocol (KAREAD: Karate and Readaptation Study)

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Introduction

In various heart diseases like coronary heart disease or heart failure, cardiac rehabilitation decreases recurrent myocardial infarction, re-hospitalisation and improves quality of life¹⁻⁴ and is recommended in the European and American guidelines in coronary and CHF patients^{5,6}.

In heart failure numerous studies have showed the beneficial effects of cardiac rehabilitation and exercise training⁷⁻¹² in reduced ejection or preserved ejection fraction¹³ and in elderly patients¹⁴.

The benefits of cardiac rehabilitation in congestive heart failure are multiple. Improvements of peak and submaximale exercise capacity, cardiorespiratory fitness, quality of life were proved^{10,14-17}.

In terms of mortality exercise-based cardiac rehabilitation may make little or non difference in all cause mortality in short term (less than 12 months) and slight reduction in all-cause mortality in medium term (> 12 months), RR 0.88, 95% CI 0.75-1.02, hospital admission for heart failure are globally reduced¹⁷.

The endurance physical activities proposed for cardiac rehabilitation (CR) widely use mainly training on cyclo-ergometers or treadmill with various intensities, duration, endurance and types: resistance training depending of the countries¹⁸.

For the last 50 years even though biking, running and different forms of physical exercises are currently used several attempts have been made to propose new types of exercises.

If we focus on the different types of activities proposed in cardiac rehabilitation centers very few have been studied.

Several studies were performed to study the effects of Yoga in coronary artery disease. After myocardial infarction yoga included in a 12 weeks rehabilitation programme has an additive effect in improving baroreflex sensitivity and dampening blood pressure variability¹⁹ but failed to show benefits in terms of major adverse cardiovascular events, self rated health, tobacco cessation or medication adherence but did show a greater return to pre-infarct activities²⁰. After coronary artery bypass in a randomized clinical trial with patients aged 35-65 year old, and a left ventricular ejection fraction > 30%, yoga shown a statistical improvement in ejection fraction, lipidic profile in particular a reduction in LDL, anxiety, quality of life questionnaire, body mass index²¹. The yoga protocol consisted in physical exercises, mental and emotionnal exercises to reach a control of mind modification based on yoga Chitta Vritti Nirodhah through “effortless blissful inner awareness”.

Another large randomized study including 3,959 patients after an acute coronary syndrome was conducted in 24 medical centers in India²⁰. The patients were randomized between a Yoga-Care program and an enhanced standard of care. The Yoga-Care program involved 13 direct contact sessions over 12 weeks with the first session delivered within 2 weeks of the cardiac event. Yoga consisted gentle yoga exercises (breath control,

meditation, relaxation) followed by discussions to improve lifestyle and psychosocial concerns. The trial did have 2 primary outcomes: occurrence of major adverse cardiovascular events (MACE) composite of all-cause mortality, myocardial infarction, stroke or emergency cardiovascular hospitalization and self-rated health at 12 weeks. The mean age was 53.4 ± 10.9 years with 86 % of male, the follow-up was of 21.6 months. The MACE occurred in 6.7 % (131) patients in the Yoga-Care group and 7.4 % (146) patients in the enhanced standard care group (HR 0.9, 95 CI 0.71-1.15, $p=0.41$, figure 2) Self-rated health was 77 in the yoga-Care group and 75.7 in the other group (fig. 2).

The return to pre-infarct activities score (reintegration to normal living index) at 12 week was 88.3 in the yoga-care group and 87.0 in the enhanced standard care group (difference in mean in favor of yoga-care group: 1.3, 95% CI 0.06-2.54, $p=0.039$). No difference in serious adverse events was reported between the two groups. This trial was the first large study showing that yoga was safe and effective in improving quality of life, return to pre-infarct activities after myocardial infarction. There was less major adverse cardiovascular in the yoga group but the study lacked statistical power to show a difference due to a lower rate of events than expected. Waltz dance for chronic heart failure patients was studied in a randomized study²². The patients were randomized between a classical rehabilitation programme and waltz dance practiced three times a week for 8 weeks at a level of 70% of peak of V_{O2} . At the completion of the study period V_{O2} , VE/V_{CO2} slope, V_{O2}/W slope, endothelium-dependant relaxation, HDL and triglycerides were improved significantly in both groups but there was no statistical difference between the two groups for ejection fraction measured by echocardiography. This study showed that waltz dancing was as effective as the classical aerobic exercise for the peak of VO_2 , VO_2 at the anaerobic threshold, VE/V_{CO2} slope. There was a higher adherence with dancing than with traditional exercise training.

Tai chi²³ has been also studied in heart failure patients comparing tai chi twice a week in a center and a recommended three times/week at home versus a control group with a classic rehabilitation program. The patients had an average age of 64 ± 13 year, left ventricular ejection fraction (LVEF) of $23 \pm 7\%$, an average class II of NYHA. At the end of the 12 week study there was a non significant improvement in the primary end point of the peak of V_{O2} in the tai-chi group (10.5 ± 3 then 11.4 ± 3 versus 11.1 ± 6 then 10.4 ± 6 in the control group, $P = 0.08$). Inversely there was a statistical improvement for the quality of life assessed with the Minnesota Living with heart failure (-25 points), an increase of the 6 min walk test (135 m, $P = 0,001$), a decrease of the natriuretic peptides (BNP – 138 pg/ml, $p=003$). It has to be noticed that there were only 15 patients in each group, that the tai chi method included slow motion movements corresponding to a moderate physical activity of 2-4 Mets and meditation. These elements may explain the non-statistical improvement of the primary end-point. Interestingly as that all secondary end-points showed benefits with tai chi this activity

might be relevant or an alternative in some patients for whom running or biking is awkward.

Current physical activities in cardiac rehabilitation could be considered boring and there is a real need to find attractive and effective physical activities. These new activities may be added to current physical activities or may replace them based on medical decisions or patient preference.

Karate is a widespread martial art activity with 10 million licence holders worldwide and we guess that this activity might be implemented in many countries and cardiac rehabilitation centres. We hypothesized that soft karate training would be at least as effective as conventional CR programs with dedicated program for patients with heart failure.

Methods

This is a two-centre study, the cardiac rehabilitation centre at the Saint Joseph Hospital, Paris, France and the other at the Corentin Celton Hospital, Issy les Moulineaux, France.

The patients included were those referred for cardiac rehabilitation and the selection criteria were as follows: age more than 18 years old, congestive heart failure with reduced left ventricular ejection fraction ($\leq 40\%$). The exclusion criteria were non-French speaking, no medical insurance.

The primary outcome was maximal oxygen consumption (VO_2) during a cardiopulmonary exercise test performed to exhaustion at the end of the study.

The secondary outcomes were quality of life as assessed by a visual analogue scale, the Kansas City Questionnaire on Heart Failure (KCCQ-12), emotional status as assessed by the Depression and Anxiety Scale -21 (DASS-21), patient satisfaction as assessed by a Likert scale, patient compliance with the protocol, key ventilatory parameters (VE/VCO_2 , QR, ventilatory reserve, etc).

The patients had undergone a cardiac screening to determine: date of birth, sex, body weight, height, aetiology of congestive heart failure, treatment, blood pressure, electrocardiogram, echocardiography with basic measurements (telediastolic and telesystolic volume and diameter of the left ventricle, ejection fraction), treadmill exercise with a protocol adapted to the patient, usually the Bruce protocol, biology (Na, K, creatinine, NT-proBNP). The quality of life questionnaires were completed during the first consultation.

At the end of the cardiac rehabilitation program another check-up was performed except the echocardiography (blood pressure, heart rate, treadmill exercise ... , QOL life questionnaires and the Likert scale of satisfaction were completed).

The patients completed a program of 40 sessions of one hour, one session per day, 5 days a week.

After cardiac screening patients were assigned by randomisation to receive either conventional cardiac rehabilitation or karate.

In the conventional group, exercise consisted of one hour of exercise per day (30 minutes of cycling or running at their first threshold determined at the initial cardiopulmonary test and 30 minutes of gymnastics). Resistance training which is now recommended for the training of CHF patients was not mandatory in our protocol in any group. The karate training used in our protocol included only dynamic exercises without specific muscle strengthening.

Interventions

Karate can be declined in fighting or kata which is a succession of codified movements (kick, punch, defense) mimicking stylish fights. Obviously for patients we did not include fights or kata but usual training without fights and potential harmful contacts. We have focused on movements that strengthen muscles and build endurance.

Several series of movements were performed during each session of one hour.

Kiba dachi Position (rider position) : shifting the axis of gravity to the right and left (Seisuke Adanaiya)



Kiba dachi position for protection (Laetitia Guyon), left punch (Kitchoth Nithiyananthan), right punch (Roger Itier)



Kicking exercises: mae geri gedan (kick) on the spot to test balance or on the move for balance control with variation of intensity low level (Jefferson Bavarois) and higher level (Seisuke Adanaiya)



1. Kiba dachi position (rider's stance), Placement of feet, knees and pelvis, Placement of head and shoulders, Shoulder relaxation exercise. Tsuki in this position requires patients to be low on their knees to more or less perform an isometric exercise for the lower limbs.

2. Shiko dachi or kiba dachi position (arching position) - static vertical movement

3. Shiko dachi or kiba dachi position - lateral movement in yori ashi (chassed steps). Back muscle strengthening + abdominal breathing

4. Kiba dachi position 2 sets of back-strengthening exercises, arms straight and arms bent

5. Kiba dachi position. series of tsukis chudan (sternum-high punches) with varying speed and intensity

6 Kick exercises :

Isa Geri : knee kick mae geri gedan (kick) on the spot to test balance, mae geri on the move to check balance - intensity variation

Combination of previous exercises : position control + tsukis + kicks

Face to face : game in which the patient tries to touch the other patient's knee.

When cycling and running are used in CR, it is easy to have a programme adapted to each patient. On the contrary, in our study, because karate is done in groups of about 10-14 people, we had to develop a strategy for the weakest and the strongest in the group. If the level of exercise is adapted for the weakest, it will not be beneficial for the strongest. Conversely, if it is adapted to the strongest, it would be too hard and discouraging for the weakest. To solve this problem, it was necessary to ask the karate teacher to perform repetitions of the same exercise several times to obtain an exhaustion of the strongest in the group (for example, sery of the

same exercise 5 times repeated 8 times). During this lapse of time if the weakest stopped for instance at the second sery he was sollicitated to perform another sery as soon as he could).

Statistical Analysis

The first patient was enrolled in September 2019 and the last in March 2022. The enrolment period was longer than expected, mainly due to the SARS-COV 2 pandemic, which led to two lock-outs and the closure of outpatient rehabilitation centres, and scared patients away from all hospital activities.

The primary endpoint was assessed following the assumption of non-inferiority, using the non-inferiority confidence interval method as recommended in the CONSORT Statement. If the upper limit of the confidence interval did not exceed the non-inferiority limit of 2 ml/kg/min, we will conclude that the karate strategy is non-inferior compared to the reference strategy. If the Karate strategy is demonstrated to be non-inferior, the superiority hypothesis will be tested.

All the secondary endpoints will be compared between the two strategies according to standard tests: Student's t-test for continuous variables, and Chi-2 test for categorical variables, or their non-parametric equivalents. The statistical analysis plan does not include a provision for correcting for multiplicity when conducting tests for secondary or other outcomes. Therefore results will be reported as mean between group differences with their 95% confidence interval.

A p-value of less than 0.05 is considered significant. Statistical analyses will be done with R, version 4.2.2 ((R Project for Statistical Computing).

Based on preliminary testing and published studies, it is planned to have 100 completed patients to have the correct power of the study.

It is amazing to see how the role of physical activity in heart disease has evolved since the 19th century. For coronary artery disease, patients were required to stay in bed for at least 6 weeks and return to ordinary life postponed as long as possible ^{24,25} even though the risk of deep venous thrombosis and pulmonary embolism were known ²⁶. Usual physical activities as walkun up stairs were prohibited for up to 12 months after myocardial infarction ²⁷. Later, in the 1950s, a new option appeared, the chair therapy, the possibility for patients to stay in a chair was proposed for 1-2 h per day ²⁸ with an improvement physically and mentally ²⁸. A few decades later, 4 weeks after a heart attack, it was allowed to walk for 3 to 5 minutes a day, and these two measures met with strong resistance from the medical community.

It is in the 70-80s that slight physical activities were proned.

You can see how far we have come in less than a century, from bed rest for several weeks to the suggestion that patients with severe heart failure and low ejection fraction might practise karate.

Results of the karead study are expected in 2025.

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Conflicts of Interest

No conflict of interest.

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