

## Clinical Research

# Early Exercise-Based Rehabilitation Improves Health-Related Quality of Life and Functional Capacity After Acute Myocardial Infarction: A Randomized Controlled Trial

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## ABSTRACT

**Background:** The purpose of this study was to evaluate the influence of an early cardiac rehabilitation (CR) program on health-related quality of life (HRQL) and functional capacity in patients who recently experienced an acute myocardial infarction (AMI). This program was initiated in the inpatient setting and was followed by an unsupervised outpatient intervention.

**Methods:** After the same inpatient care plan, low-risk patients who experienced an AMI were randomized into 2 groups: (1) a control group (CG) ( $n = 43$ ) entailing usual care and (2) an intervention group (IG) ( $n = 45$ ) entailing outpatient (unsupervised) CR primarily centered on a progressive walking program. Initially, all patients underwent a supervised exercise program with early mobilization beginning 12 hours after an AMI. On hospital discharge, all patients were classified according to cardiovascular risk. Quality of life was evaluated by the MacNew Heart Disease HRQL questionnaire 30 days after discharge. Functional capacity was determined by a 6-minute walk test (6MWT) distance on the day of inpatient discharge as well as 30 days afterward.

## RÉSUMÉ

**Introduction :** Le but de cette étude était d'évaluer l'influence d'un programme de réadaptation cardiaque (RC) précoce sur la qualité de vie liée à la santé (QdVS) et la capacité fonctionnelle des patients qui avaient récemment subi un infarctus du myocarde aigu (IMA). Ce programme qui avait été mis en place en milieu hospitalier était suivi d'une intervention ambulatoire non supervisée.

**Méthodes :** Après le même plan de soins en milieu hospitalier, les patients exposés à un risque faible qui subissaient un IMA étaient répartis de manière aléatoire en 2 groupes : 1) un groupe témoin (GT;  $n = 43$ ) comportant les soins habituels; 2) un groupe d'intervention (GI;  $n = 45$ ) comportant une RC (non supervisée) ambulatoire principalement axée sur un programme de marche progressive. Au début, tous les patients entreprenaient un programme supervisé d'exercices favorisant la mobilisation précoce 12 heures après l'IMA. Au congé de l'hôpital, tous les patients étaient classifiés selon leur risque cardiovasculaire. La qualité de vie était évaluée à l'aide du questionnaire de QdVS en cardiologie MacNew 30 jours après le congé. La capacité fonctionnelle était déterminée par la distance parcourue au test de

Health-related quality of life (HRQL)—encompassing physical, emotional, and social well-being—is an important indicator of health outcomes in patients with coronary artery disease (CAD),<sup>1</sup> which is the leading cause of morbidity and

mortality worldwide and has a profound negative impact on HRQL as well as functional capacity.<sup>2</sup>

Current best practice patterns have multiple therapeutic targets, including prognostic, functional, symptomatic, and HRQL improvements. Cardiac rehabilitation (CR) is integral to optimizing recovery in patients with CAD who have experienced an acute myocardial infarction (AMI), helping them to return to an active and productive life. However, more work is needed to understand the clinical benefits of CR, not only regarding morbidity and mortality but also regarding HRQL.<sup>2</sup> There are multiple approaches and tools that have been used to assess changes in HRQL, both generic

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See page 313 for disclosure information.

**Results:** The HRQL global score was higher in the IG compared with the CG 30 days after discharge ( $P < 0.001$ ); physical and emotional domain scores were both significantly higher in the IG ( $P < 0.001$ ). Furthermore, the IG showed a greater 6MWT distance compared with the CG ( $P < 0.001$ ).

**Conclusions:** A CR program based on early progressive exercises, initiated by supervised inpatient training and followed by an unsupervised outpatient program, improved HRQL and functional capacity in patients at low cardiovascular risk who recently experienced an AMI.

and AMI-specific instruments, although the latter approach has been used less frequently.<sup>3</sup> In addition, the majority of CR trials have been initiated several months after an AMI has occurred. This time gap from the event to CR initiation may lead to less than optimal improvements that could be acquired with early initiation of CR.<sup>4</sup> Moreover, although CR has proved to be beneficial, participation remains suboptimal because of numerous factors, including poor referral, cost, lack of perceived value, and a limited number of centres offering supervised CR.<sup>5,6</sup> Interestingly, a systematic review has shown favorable effects of unsupervised CR.<sup>7</sup>

Given the current knowledge gaps, the objective of the current study was to evaluate the influence of an early CR program on HRQL and functional capacity in patients who recently experienced an AMI. Specifically, this program was started in the inpatient acute care setting and was followed by an unsupervised outpatient intervention.

## Methods

This study was performed at the São Paulo Hospital Cardiology Unit of the Federal University of São Paulo between May 2010 and March 2013. Before enrollment, all patients were informed about the study and signed written consent forms. This study was approved by the Clinical Ethical Research Committee of the institution.

## Selection of patients

Within the first 12 hours of intensive care unit admission, participants were prospectively selected among patients experiencing an AMI and undergoing percutaneous coronary intervention (PCI) with or without chemical reperfusion therapy. Patients included in this study ranged between 18 and 70 years of age with a confirmed AMI diagnosis (ie, serum cardiac enzyme evaluation), with or without ST-segment elevation, and with clinical signs of reperfusion. Patients with cardiogenic shock, recurrent angina, a neuromuscular disease diagnosis, or hemodynamic instability; those receiving mechanical ventilation; those with atrial and ventricular arrhythmias leading to hemodynamic compromise; those who had a previous AMI; those with an inability to undergo pulmonary function testing; those who had cardiac arrest; those with poor medication adherence or nonperformance of the protocol; and those who underwent exclusive chemical reperfusion were excluded. Patients with chronic lung disease

marche de 6 minutes (TM6M) le jour du congé de l'hôpital ainsi que 30 jours après.

**Résultats :** Le score global de la QdVS était plus élevé dans le GI que dans le GT 30 jours après le congé ( $P < 0,001$ ); les scores sur les plans physique et émotionnel étaient plus élevés dans le GI ( $P < 0,001$ ). De plus, le GI parcourait une plus grande distance au TM6M que le GT ( $P < 0,001$ ).

**Conclusions :** Un programme de RC basé sur des exercices progressifs précoces, qui débute par un entraînement supervisé en milieu hospitalier et est suivi d'un programme ambulatoire non supervisé, améliorait la QdVS et la capacité fonctionnelle des patients exposés à un faible risque cardiovasculaire qui avaient récemment subi un IMA.

confirmed by pulmonary function testing according to The American Thoracic Society (ATS) were also excluded.<sup>8</sup>

## Study design

**Stage I.** The patients underwent a supervised early mobilization exercise program twice a day beginning 12 hours after the AMI (the inpatient phase) according to the American Heart Association recommendations.<sup>9</sup> Initial energy expenditure during exercise training was estimated at 2 metabolic equivalents (METs), with an incremental progressive increase to an estimated 4 MET intensity.<sup>10</sup> The supervised exercise program performed during the inpatient phase was terminated if there were signs of exercise intolerance, low cardiac output (cyanosis, pallor, or nausea), bradycardia, a drop in systolic blood pressure  $> 15$  mm Hg compared with baseline, an excessive rise in systolic blood pressure defined as  $> 200$  mm Hg, a rise in diastolic blood pressure during exercise  $> 110$  mm Hg, chest pain, fatigue rated  $\geq 6$  of 10 on the perceived exertion Borg (PEB) scale, or electrocardiographic signs of cardiac ischemia or ventricular arrhythmias, or both.<sup>9</sup>

During the exercise program, patients were instructed to maintain a PEB scale rating between 4 and 5 (scale 0-10), corresponding to mild-moderate exercise intensity, according to current recommendations.<sup>11</sup>

On hospital discharge, patients were classified in relation to cardiovascular risk according to the American Association of Cardiovascular and Pulmonary Rehabilitation guidelines.<sup>12</sup> Only patients deemed to be at low cardiovascular risk were randomized into 1 of 2 groups: (1) the control group (CG) ( $n = 43$ ), who received usual care and (2) the intervention group (IG) ( $n = 45$ ), who were instructed to participate in an unsupervised walking program.

In both groups, the patients underwent an educational program that included general information about their cardiac diagnosis, sexual activity, the importance of continuing to exercise, nutritional recommendations, and compliance with their pharmacologic regimen. In an attempt to improve adherence, an informative brochure was given to the patient at hospital discharge, and weekly calls were made as follow-up. All patients were scheduled to return 30 days after hospital discharge for re-evaluation.

*Randomization and blinding.* A random sequence was generated by a computer system, and allocation secrecy was accomplished by numbered sealed opaque envelopes. The outcomes measures were assessed by the same health professional, who

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