

# Unsupervised Rehabilitation: effects of Exercise Training over the Long Run

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**Objective** - To assess the safety and efficacy of unsupervised rehabilitation (USR) in the long run in low-risk patients with coronary artery disease.

**Methods** - We carried out a retrospective study with 30 patients divided into: group I (GI) - 15 patients from private clinics undergoing unsupervised rehabilitation; group II (GII) - control group, 15 patients from ambulatory clinic basis, paired by age, sex, and clinical findings. GI was stimulated to exercise under indirect supervision (jogging, treadmill, and sports). GII received the usual clinical treatment.

**Results** - The pre- and postobservation values in GI were, respectively:  $VO_2$  peak (mL/kg/min),  $24 \pm 5$  and  $31 \pm 9$ ;  $VO_2$  peak/peak HR:  $0.18 \pm 0.05$  and  $0.28 \pm 0.13$ ; peak double product (DP peak):  $26,800 \pm 7,000$  and  $29,000 \pm 6,500$ ; % peak HR/predicted HRmax:  $89.5 \pm 9$  and  $89.3 \pm 9$ . The pre- and post- values in GII were:  $VO_2$  peak (mL/kg/min),  $27 \pm 7$  and  $28 \pm 5$ ;  $VO_2$  peak/peak HR:  $0.2 \pm 0.06$  and  $0.2 \pm 0.05$ ; DP peak:  $24,900 \pm 8,000$  and  $25,600 \pm 8,000$ , and % peak HR/predicted HRmax:  $91.3 \pm 9$  and  $91.1 \pm 11$ . The following values were significant: preobservation  $VO_2$  peak versus postobservation  $VO_2$  peak in GI ( $p=0.0063$ ); postobservation  $VO_2$  peak in GI versus postobservation  $VO_2$  peak in GII ( $p=0.0045$ ); postobservation  $VO_2$  peak/peak HR GI versus postobservation peak  $VO_2$ /peak HR in GII ( $p=0.0000$ ). The follow-up periods in GI and GII were, respectively,  $41.33 \pm 20.19$  months and  $20.60 \pm 8.16$  months ( $p<0.05$ ). No difference between the groups was observed in coronary risk factors, therapeutic management, or evolution of ischemia. No cardiovascular events secondary to USR were observed in 620 patient-months.

**Conclusion** - USR was safe and efficient, in low-risk patients with coronary artery disease and provided benefits at the peripheral level.

**Key words:** atherosclerotic coronary artery disease, exercise test, unsupervised rehabilitation

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Cardiac rehabilitation is currently a routine procedure for the treatment of atherosclerotic coronary artery disease. It may be performed at specialized centers (supervised rehabilitation), at home, or in public places with long-range supervision (unsupervised rehabilitation)<sup>1</sup>. Unfortunately, supervised rehabilitation has benefited few patients, even in developed countries, due both to logistic difficulties and high operational costs<sup>2</sup>. The major objective of unsupervised rehabilitation is for patients to exercise under indirect supervision, extending the practice of exercising to a large number of patients considered low risk for ischemia when practicing physical exercise<sup>3</sup>. In this context, unsupervised rehabilitation has been considered a safe activity<sup>4</sup>.

Studies reported in the medical literature on unsupervised rehabilitation are few. The first guidelines for unsupervised rehabilitation were published by Williams et al in 1981<sup>5</sup>. Since the first study<sup>6</sup> until the present date, 13 original articles and a summary have been reported, adding to a total of 1,230 patients with coronary artery disease exercising according to protocols from 4 to 24 weeks after an acute coronary event<sup>7-18</sup>. In Brazil, only recently have the guidelines and the first experiences on unsupervised rehabilitation been published<sup>19-21</sup>.

Patients with antecedents of coronary artery disease spontaneously restrict their physical activity, independent of medical guidance. This defensive behavior interferes with work, recreation, and personal activities, sexual relationships included. Several studies have shown the importance of physical training in these patients with improvement in health status and psychological profile<sup>1-4,19</sup>.

The objectives of this study were as follows: 1) to assess the performance of patients with stable atherosclerotic coronary artery disease at low risk for developing ischemia during exercise practice<sup>5</sup> in the long run using a protocol of unsupervised rehabilitation; and 2) to assess efficacy, safety, and feasibility of unsupervised rehabilitation conducted from the medical office in our environment.

## Methods

The design of the protocol was that of a case-control study<sup>22</sup>. In a retrospective analysis of medical records from a private practice, we consecutively selected 20 patients with stable atherosclerotic coronary artery disease confirmed on coronary angiography who were considered at low risk for developing ischemia during exercise according to the modified criteria of Williams et al<sup>5</sup> (chart I: criteria 2, 3, and 4). These patients underwent a regular program of unsupervised rehabilitation during a period longer than 12 months between 1982 and 1996. From this group, 15 patients were selected to undergo unsupervised rehabilitation and constituted group I (GI). Four patients were excluded due to insufficient information in their medical records, and another patient was excluded due to the impossibility of obtaining parity in the control group. GI was compared with the control group (GII), which comprised 15 patients selected from the outpatient clinic for coronary artery disease of the cardiology department of the Escola Paulista de Medicina (UNIFESP-EPM). These GII patients were selected in a retrospective assessment of medical records and were paired by age, sex, clinical findings, and ambulatory follow-up longer than 12 months in the same period. Each group had 13 males and 2 females with angina pectoris (n=8), previous myocardial infarction (n=8), antecedents of coronary angioplasty (n=2), and revascularization surgery (n=6). Ages of GI and GII patients were 64±10 and 63±10 years, respectively. The distribution of the major coronary risk factors was similar in both groups as follows (GI and GII, respectively): smoking (6 vs 5 cases), arterial hypertension (9 vs 11 cases), hypercholesterolemia (9 vs 10 cases), and diabetes mellitus (4 vs 5 cases).

According to the protocol, GI patients were informed about the risks and benefits of physical training. Initially, all patients underwent clinical and laboratory assessments to

stratify the exercise risk<sup>5</sup>. Then, they were motivated to exercise according to their own preferences and availabilities after an extensive explanation about the fundamentals of physical conditioning. The patients were periodically reassessed on an outpatient basis and were advised to suspend exercise practice and to look for medical assistance in case of incidents. The exercise program comprised 3 to 5 sessions per week, lasting 30 to 60 minutes each and reaching 70% to 80% of the useful functional capacity (maximal exercise level in the absence of symptoms or clinical or electrocardiographic signs)<sup>23</sup>. Physical training comprised jogging (n=12), exercising on a treadmill (n=2), swimming (n=2), tennis (n=1), and soccer (n=1). The patients who chose swimming and tennis were used to those sports modalities. The patient who chose soccer despite the warning that that modality of exercise was inadequate and even risky kept that practice on a regular basis<sup>24</sup>.

GII patients were routinely followed up in the outpatient clinic with usual hygienic and dietary measures and clinical treatment.

At the beginning and end of the observation period, GI and GII patients underwent conventional exercise testing using their usual medications. On the initial assessment, the following protocols were used: 1) in GI – Bruce (n=5), classic Ellestad (n=5), attenuated Ellestad (n=1), and Astrand (n=4); 2) in GII – Bruce (n=12) and modified Naughton (n=3). On the final assessment, the following protocols were used: 1) in GI – Bruce (n=5), classic Ellestad (n=8), and Astrand (n=2); 2) in GII – Bruce (n=15). VO<sub>2</sub> peak was estimated according to the formulae and nomograms of the protocols used and the reports of the tests. For standardization, the exercise tests were reassessed according to the criteria established by the Consenso Nacional de Ergometria<sup>25</sup>. The estimations of VO<sub>2</sub> peak were then recalculated according to the recent standardization<sup>26</sup> for the Bruce<sup>27</sup>, Ellestad<sup>28</sup> and Naughton<sup>29</sup> tests, and correction factors were applied for the cycloergometric tests<sup>30</sup>.

The statistical analysis was performed with the Student *t* test (2-tailed), and the values of p<0.05 were considered significant.

## Results

The observation periods for GI and GII patients were 41.3±20.2 and 20.6±8.2 months, respectively (p<0.05). GI patients were followed up for a variable period of 19 to 79 months (median of 31 months), which comprised 620 patient-months of observation with no cardiovascular accidents secondary to the program.

Figures 1, 2, 3, and 4 summarize the results using VO<sub>2</sub> peak values obtained in the medical records. In GI, the following pre- and postobservation values were respectively obtained: VO<sub>2</sub> peak (mL/kg/min): 24±5 and 31±9; VO<sub>2</sub> peak/HR peak: 0.18±0.05 and 0.28±0.13; DP peak: 26,800±7,000 and 29,000±6,500; and %HR peak/predicted HRmax: 89.5±9 and 89.3±9. In GII, the following pre- and postobservation values were respectively obtained: VO<sub>2</sub> peak (mL/kg/min):

Chart I – Criteria for selecting patients for unsupervised rehabilitation according to Williams et al<sup>5</sup>

<ol style="list-style-type: none"> <li>1. Previous supervised training during 6 months.</li> <li>2. Absence of the following symptoms, signs, and antecedents:           <ol style="list-style-type: none"> <li>2.1. VO<sub>2</sub> peak &lt; 6 METS;</li> <li>2.2. Angina or signs of myocardial ischemia during exercise testing, when no medication is used, with VO<sub>2</sub> &lt; 6 METS or HR &lt; 120 bpm;</li> <li>2.3. Marked ventricular dysfunction – 3<sup>rd</sup> cardiac sound present, cardiomegaly, or left ventricular ejection fraction &lt; 0.35 at rest or during exercise;</li> <li>2.4. Abnormal hemodynamic response during exercise testing – abnormal blood pressure response, drop in left ventricular ejection fraction &gt; 10%;</li> <li>2.5. Complex ventricular arrhythmias;</li> <li>2.6. Corrected QT interval &gt; 440 msec;</li> <li>2.7. Antecedents of ventricular fibrillation in the absence of acute myocardial infarction.</li> </ol> </li> <li>3. Incapacity to perform self-monitoring, to keep within the limits of the exercises prescribed, and to adhere to the program.</li> <li>4. Knowledge about the basic principles of aerobic training.</li> </ol>
MET - metabolic unit (1 MET = 3.5 mL/kg/min); HR – heart rate.

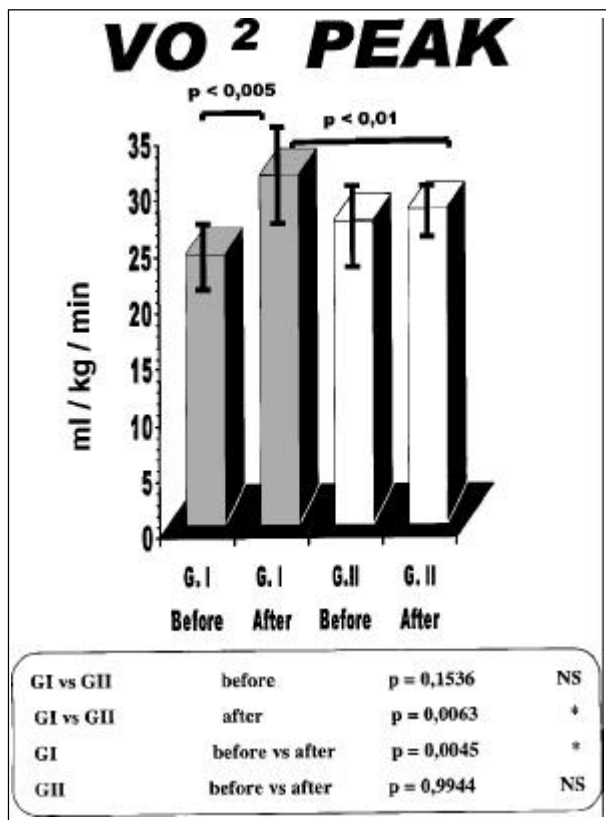


Fig. 1 – Peak VO<sub>2</sub> before and after follow-up in groups I (experimental) and II (paired control).

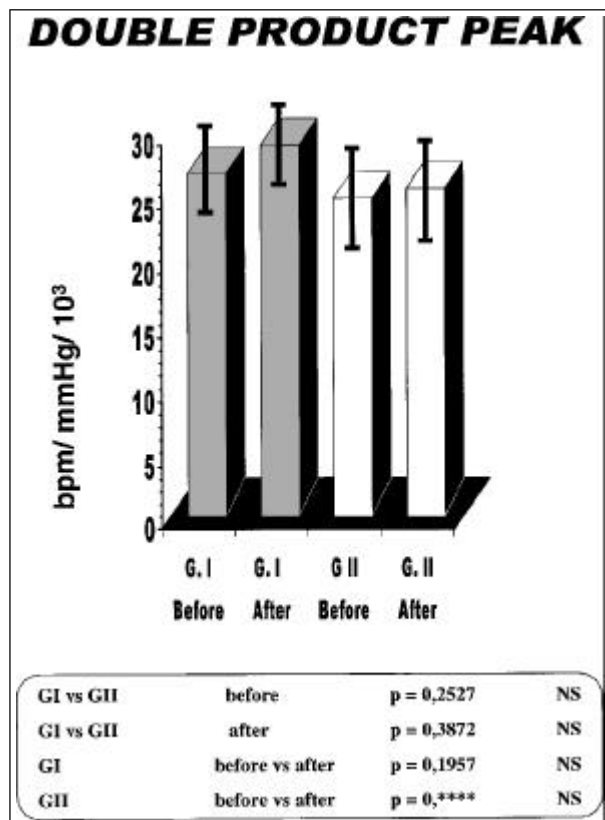


Fig. 3 – Peak double product before and after follow-up in groups I (experimental) and II (paired control).

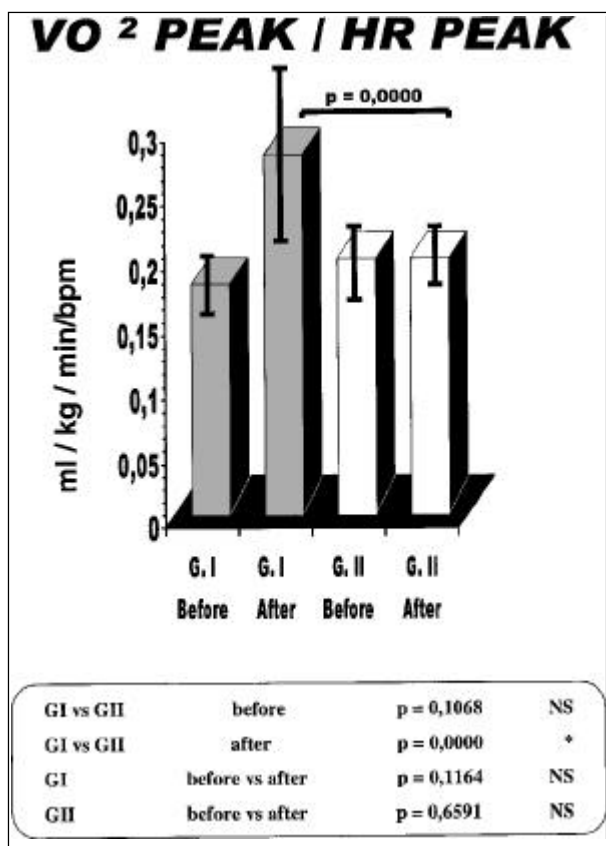


Fig. 2 – Peak VO<sub>2</sub>/peak HR ratio before and after follow-up in groups I (experimental) and II (paired control).

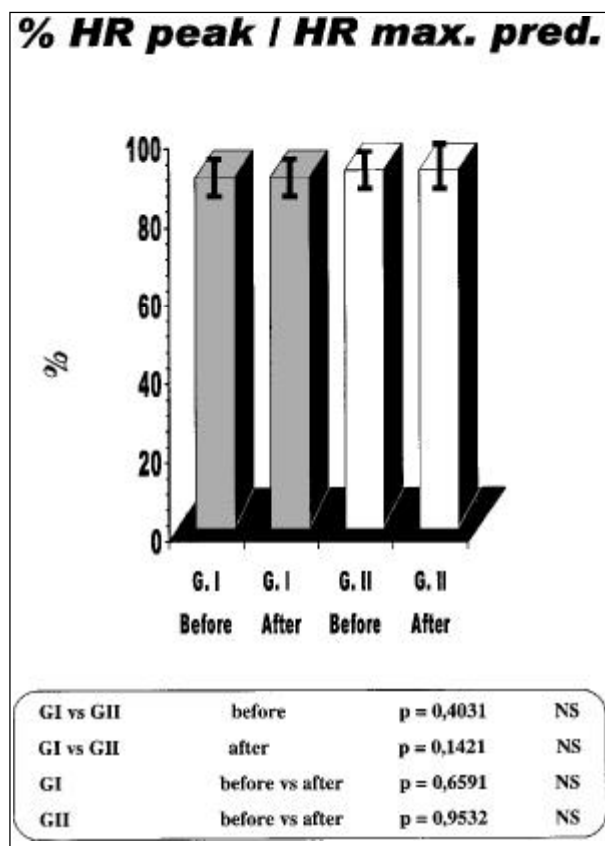


Fig. 4 - Peak HR/predict maximal HR\*(%) before and after follow-up in groups I (experimental) and II (paired control). \* Predict maximal HR = 220 – age (in years).

27±7 and 28±5; VO<sub>2</sub> peak/HR peak 0.2±0.06 and 0.2±0.05; DP peak: 24,900±8,000 and 25,600±8,000; and % HR peak/predicted HRmax: 91.3±9 and 91.1±11.

The statistical analysis showed the following statistically significant differences: pre- VO<sub>2</sub> peak versus post- VO<sub>2</sub> peak in GI (p=0.006); post- VO<sub>2</sub> peak in GI versus post- VO<sub>2</sub> peak in GII (p=0.004), and post- VO<sub>2</sub> peak/HR peak in GI versus post- VO<sub>2</sub> peak/HR peak in GII (p=0.0001).

The evolution of the myocardial ischemia pattern during exercise testing was similar in GI and GII (tab. I). No myocardial revascularization was performed in either group during the observation period.

## Discussion

The results of this study are the 1<sup>st</sup> published about unsupervised rehabilitation in the long run in the specialized literature<sup>20,21</sup>.

Currently, only 25% of the patients with coronary artery diseases are estimated to have access to clinics for supervised rehabilitation<sup>2</sup>. Logistic, financial, and social difficulties hinder the wide use of supervised rehabilitation in that population. In our environment, clinics specializing in supervised rehabilitation are lacking. In that context, unsupervised rehabilitation allows patients considered at low risk for ischemic events to exercise in public places and even in their homes. In reality, the term “unsupervised rehabilitation,” which has been widely spread, is not appropriate, because the patient is required to maintain periodic contact with the physician. Even though multidisciplinary teams have been advised to work in unsupervised rehabilitation, it is the assistant physician who accounts for the patient’s admission, prescription, assessment of clinical repercussions, and discharge from the training program<sup>31</sup>. In our opinion, the term “semi-supervised rehabilitation” would be more appropriate<sup>32</sup>.

In the present study, patients were advised about the exercise program during their usual medical visits. This proved feasible, and, considering the importance of the physician-patient relationship, this could be an advantage for the better acceptance of the program. Several guidelines on unsupervised rehabilitation have been published<sup>5,19,32-35</sup>. According to most of these guidelines, unsupervised rehabilitation should start with a brief period of training in spe-

cialized clinics. As happened in our study, in several cases that period can be replaced by the delivery of speeches and theoretical-practical instructions.

In our study initiated in 1982, the criteria for patient selection proposed by Williams et al<sup>5</sup> were used. It is worth noting that unsupervised rehabilitation is appropriate for low-risk patients with coronary artery diseases. The criteria for defining low-risk patients are very similar, except for some small differences<sup>4,5,19</sup>. The patients in our study were in a stable, chronic phase and had not undergone a resting period due to a recent coronary event. Despite this, the mean increase in VO<sub>2</sub> peak reached 29% during training longer than 12 months, confirming the benefit of exercise in the long run. After physical training, VO<sub>2</sub> peak (mL/kg/min) increased from 24±5 to 31±9 in GI. These data correspond to the mean elevation of 2 METS, which can significantly increase the patient’s functional class and interfere with work, recreation, and personal activities, sexual relationships included<sup>36</sup>. In the initial phase, both groups had similar VO<sub>2</sub> peak values. In GII, no significant variation was observed in VO<sub>2</sub> peak, confirming that the final values recorded in GI were due to physical training.

Because this was a retrospective study, uniformity in the protocols of the exercise test was not possible. However, Bruce and Ellestad protocols were used in 85% of the exercise tests. Those protocols had a high correlation in the regression analyses, and no significant differences were observed in the measurements of VO<sub>2</sub> peak, peak heart rate, and peak blood pressure<sup>37</sup>. In 10% of the exercise tests, the Astrand protocol for the cycloergometer was used. The mean VO<sub>2</sub> peak on a bicycle ranged from 89% to 95% of the values found on treadmills, and a 10% increase in the values obtained with the cycloergometer was considered corresponding to the values obtained on the treadmill<sup>30</sup>. In this way, all calculations and statistical analyses referring to the VO<sub>2</sub> peak estimates were redone, this correction included<sup>30</sup>, according to recent standardization<sup>26</sup>. Nevertheless, the statistical analysis also showed similar results.

Our results are in accordance with those in the literature<sup>6-18</sup> that report a greater aerobic power in the groups trained as compared with that in untrained groups. However, unlike our sample, which comprised patients selected who were in a stable, chronic phase, other studies lack values of preconditioning aerobic power, because they were started after recovery from an acute coronary event. Usually, 23% elevations of VO<sub>2</sub> peak are reported during a conditioning period ranging from 1 to 6 months<sup>6,8,9,10,12,17</sup>, as is a 19% elevation of the mean anaerobic threshold<sup>8,10,11</sup>. After 4 weeks of training, significant elevations in the maximal aerobic power by 14% and in the 2 mmol lactate threshold by 19% were detected<sup>18</sup>.

Maximal heart rate obtained during exercise testing may be predicted using equations and serve to assess whether the effort was sufficient. Usually in patients with coronary artery disease, maximal heart rate is assessed using the heart rate measured at the peak of exertion, which is called peak heart rate. Maximal heart rate decreases with

**Table I – Evolution of the pattern of myocardial ischemia during exercise testing in pre- and postobservation GI and GII**

Evolution	Group I	Group II
pre ET - to post ET -	7 cases	10 cases
pre ET + to post ET +	2 cases	3 cases
pre ET - to post ET +	3 cases	1 cases
pre ET + to post ET -	3 cases	1 cases

pre ET - preobservation nonischemic exercise test; pre ET+ - preobservation ischemic exercise test; post ET- postobservation nonischemic exercise test; post ET+ - postobservation ischemic exercise test.

age. Therefore, for a long-term assessment of patients of different ages, the percentage reached by the peak heart rate is more appropriate, because it is a linear function of the exercised percentage of  $VO_2$  peak<sup>38</sup>. In GI and GII, the percentages of the predicted maximal heart rate reached during the tests were 89% and 91%, respectively ( $p > 0.05$ ). In this way, possible biases of  $VO_2$  peak measurement were excluded and the degrees of quality of the exercise tests performed were validated.

The  $VO_2$  peak/HR peak relation had not been analyzed in previous publications. In our study, a significant elevation of the pre- and postconditioning  $VO_2$  peak/HR peak relation occurred in GI, showing a greater efficacy of myocardial work and confirming the benefit of exercising in the long run. However, maintenance of double product levels, which usually render myocardial  $O_2$  consumption, reflects a predominantly peripheral response to physical exercise.

For unsupervised rehabilitation, data in the literature are controversial regarding the repercussions of training on ventricular function. After 6 months of exercising, a mild elevation in ejection fraction at rest has been reported only in patients with reduced ventricular function<sup>11</sup>. In a protocol for physically disabled individuals, significant elevations in ejection fraction and percentage of systolic shortening occurred at peak exertion, maintaining the values at rest unaltered<sup>14</sup>. However, elevations of the systolic volume at rest and during exercise, with no alteration in the ejection fraction, have been reported in patients undergoing high-intensity exercising; these values remained unaltered in the subgroup of patients exercising at low intensity<sup>17</sup>.

In our study, the pattern of evolution of myocardial ischemia observed during exercise testing showed no significant alterations, being similar in both groups. In a pioneering study, Miller et al<sup>6</sup> reported ischemic tests in 42% and 35% of the patients at the beginning and end of the protocol, respectively.

No conclusive data about the risk of unsupervised rehabilitation exist. As this was a retrospective study, we were not able to assess the patients' compliance with the exercise program based on the medical records. However, no accident occurred in 620 patient-months of observation.

The compliance reported by other authors has been satisfactory in prospective protocols of unsupervised rehabilitation. In the literature, compliances of 89% and 72%, respectively, have been reported after up to 11 and 26 weeks of conditioning<sup>6</sup> and of 91% and 83%, respectively, by the end of 4 and 24 weeks of training<sup>9</sup>. Considering an eventual compliance of 70% and an average training of 3 sessions per week, no accidents would have been reported in approximately 5,200 patient-hours of training.

The risk of cardiocirculatory arrest in unsupervised rehabilitation was 1/6,000 patient-hours in the 1970s, decreasing to 1/120,000 in the 1990s. Recently, risks of cardiocirculatory arrest of 1/98,717 patient-hours (supervised rehabilitation) and of 1/70,000 patient-hours (unsupervised rehabilitation) have been reported<sup>4</sup>. According to these findings, approximately 1 cardiocirculatory arrest occurred for each group of 100 patients exercising uninterruptedly for 5 years, in a regimen of 3 sessions per week. The availability of emergency devices in public places used for unsupervised rehabilitation can be extremely useful<sup>39,40</sup>. In our relatively small sample comprising 5,200 patient-hours of training, no coronary event related to training occurred, which is in accordance with reports in the specialized literature.

Considering the limitations of ours, new prospective studies are required with larger samples subdivided into specific groups of patients with atherosclerotic coronary artery disease. These results may be partially due to the enthusiasm for exercise in the selected patients. Subsequent studies using proper questionnaires may confirm an improvement in quality of life.

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