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## **Evaluation of Maintained Physical Capacity 1-yr After Coronary Patient Cardiac Rehabilitation (EMAP): A FRENCH MULTICENTER STUDY**

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► **To cite this version:**

Bruno Pavy, Sophie Kubas, Cécile Rocca, Erick Merle, Hélène Kerros, et al.. Evaluation of Maintained Physical Capacity 1-yr After Coronary Patient Cardiac Rehabilitation (EMAP): A FRENCH MULTICENTER STUDY. *Journal of Cardiopulmonary Rehabilitation and Prevention*, 2022, Publish Ahead of Print (4), 10.1097/HCR.0000000000000684 . hal-03659560

**HAL Id: hal-03659560**

**<https://hal.science/hal-03659560>**

Submitted on 29 Jun 2022

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1 **ORIGINAL INVESTIGATION**

2 **Full title**

3 **Evaluation of Maintained physical caPacity one year after coronary patient cardiac**  
4 **rehabilitation (EMAP): A French multicenter study.**

5

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11

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25

26 **Short running title**

27 One-year follow-up of cardiac rehabilitation

28

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36 **Key words**

37 cardiac rehabilitation; one-year follow-up; physical capacity

38

39 All authors declare no conflicts of interest

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## 1 INTRODUCTION

2

3 Secondary prevention after a coronary event is essential, as lifestyle changes are difficult to  
4 implement<sup>1</sup>. The benefits of cardiac rehabilitation (CR) to reduce cardiovascular morbidity and  
5 mortality are widely recognized in coronary artery disease (CAD) patients<sup>2-4</sup>. Multidisciplinary  
6 management with therapeutic patient education is particularly effective and recommended. This  
7 CR, modifies medical cardiovascular risk factors (hypertension, diabetes,  
8 hypercholesterolemia) and lifestyle (diet, smoking, sedentary/physical inactivity levels)<sup>5-8</sup>.

9 Exercise training improves cardiorespiratory fitness (CRF), which is a major mortality  
10 prognostic marker. 1 metabolic equivalent of the task (MET) increase was associated with 8 to  
11 35% reduction in risk of mortality (depending on the studied population characteristics)<sup>9</sup>. In  
12 CAD patients, exercise training (anti-ischemic, antiarrhythmic, antithrombotic and psychologic  
13 effects) improves endothelial function and participates to CR benefits<sup>10</sup>.

14 A large German multicenter study, whose CR modalities are similar to those used in France,  
15 observed a decrease in mortality after CR. This study reported a higher physical activity (PA)  
16 in the follow-up, but without any CRF evaluation<sup>11</sup>. In a large UK community-based CR  
17 program with a 10 year mean follow-up, the baseline CRF which increased by mean 1.1 MET  
18 was the main survival rate predictor. However, the RAMIT study results with an average gain  
19 of only 0.5 MET after the CR program reported no effects on mortality<sup>12,13</sup>.

20 The limits from self-reported data PA practice during phase III rehabilitation by patients are  
21 proven<sup>14</sup>. Thus, it seems more appropriate to evaluate the patient CRF changes after the CR  
22 program to study the sustainability of its benefits.

23 The aim of this prospective study was to follow the evolution of the CRF level in CAD  
24 patients before, at the end, and one year after their CR program.

## 25 METHODS

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This multicenter study was carried out in 16 French CR centers which included at least 10 consecutive coronary patients. Multicenter study ethical approval was obtained with the personal protection committee (n°2015-S4). All participants provided written informed consent.

*CRITERIA OF INCLUSION*

All patients must have undergone within the previous 3 months an acute coronary syndrome (ACS), and / or percutaneous coronary intervention (PCI) revascularization, or coronary artery bypass graft (CABG). They had to participate in a CR stay including a physical training program with at least 5 sessions (inpatient or outpatient), performed two cycle ergometer exercise tests, and obtained a progression of at least 10 watts.

*CRITERIA OF EXCLUSION*

Patient refusal, misunderstanding, co-morbidity preventing PA, CR exclusion criteria according to the French cardiac rehabilitation guidelines<sup>15</sup>.

*PROTOCOL*

*Cardiorespiratory fitness assessment:*

Each patient had to perform 3 maximal or symptom-limited progressive exercise tests (ET) on a cycle ergometer. The exercise protocol usually started at 30 watts, with 10 watt increments every minute (or more to achieve an optimal 8–12 minutes test duration), until exhaustion or symptoms. The maximum validated workload was that of the last step maintained for at least 30 seconds. The initial ET (ET1) was performed prior to the physical training program, ET2 at the completion of the training program, and ET3 one year thereafter. The FRIEND formula was

1 chosen to estimate the CFR because it is more accurate than the ACSM formula<sup>16</sup>. To allow for  
2 accurate comparisons, the three ETs were performed using the same protocol while the patients  
3 were under medication.

4

5 *Cardiac rehabilitation program:*

6 The cardiac rehabilitation program included a therapeutic education program and at least 5  
7 exercise sessions including continuous or interval-training endurance, resistance, and  
8 respiratory training. Physical training was practiced in groups, either residents (5 sessions per  
9 week) or outpatients (3 to 5 sessions per week), over a 3 to 7week period.

10

11 *Data collection:*

12 Demographic data gathered at the end of the CR and one year later concerned blood pressure,  
13 glycemia, LDL and HDL cholesterol levels. Diabetes was determined through positive blood  
14 tests (fasting blood sugar >1.26g/L) or current antidiabetic drug medication. Hypertension was  
15 confirmed if blood pressure >140/90 mmHg, or patient under current antihypertensive  
16 medication.

17

18 *STATISTICAL ANALYSIS*

19 Quantitative variables were expressed as mean  $\pm$  standard deviation and qualitative variables  
20 as percentages. The comparison performed concerned the evolution of the parameter values  
21 observed during the 3 stages (pre-CR, post-CR and 1-year post-CR) of the study. Comparisons  
22 of the variables were conducted using analysis of variance (ANOVA) and Kruskal-Wallis  
23 according to distribution. We used Bonferroni's adjustment to identify potential differences  
24 among the individual three exercise tests. Then, we used independent t-test or Mann-Whitney  
25 U test for analysis of subgroups, as appropriate. The Chi-square test was used for the

1 percentages comparison and the Spearman test was used to assess the correlation between  
2 variables. In all cases the significance level was set at  $P < .05$ . Statistical analysis was performed  
3 using the software Stat-EL (www.adscience.fr)

4

## 5 **RESULTS**

6

### 7 *POPULATION (see Figure 1)*

8 From December 2015 to December 2016, in 392 eligible patients, 117 were excluded. 18  
9 patients declined, 22 patients did not complete the CR (10 dropped out, 1 severe heart failure,  
10 1 depressive syndrome, 10 without details), 16 did not perform two cycle ergometer ETs (7  
11 with treadmill, 9 too tired), 7 patients did not progress ( $< 10$  watts), 14 patients did not attend  
12 at least 5 training sessions, 15 patients were unable to participate (cognitive impairment,  
13 language barriers), 19 patients lived too far away, and 6 others were also excluded (two were  
14 already included in another protocol, 1 pericarditis, 1 severe ventricular dysfunction, 1 with a  
15 lifevest and 1 severe peripheral artery disease). Therefore, 275 patients were included in the  
16 study. Among them, 16 (6%) were lost during the 1-year follow-up: 2 non-cardiac deaths, 10  
17 refused, and 4 did not attend the follow-up. Thus, 259 patients completed the whole study.

18

### 19 *TRAINING PROGRAM*

20 Total training session number was  $17 \pm 8$ , with an average duration of  $122 \pm 45$  min per session.  
21 The global training volume was  $34.2 \pm 16$  h for an average duration of  $5 \pm 3.3$  weeks (133  
22 outpatients over a 6.9 week mean duration CR program and 126 inpatients for a 3.1 week mean  
23 duration program). The training volume was  $41.7 \pm 15$  hours versus  $26.2 \pm 15$  ( $P < .001$ )  
24 respectively for outpatients and inpatients. Medications were unchanged after one year.

25

1 *BASELINE DATA*

2 Characteristics are summarized in Table 1.

3 The population was predominantly male (89%) with an average age of 60.

4 200 patients (77%) had ACS, including 149 ST-elevation myocardial infarctions. Their left  
5 ventricular ejection fraction was  $> 50\%$ ,  $35\text{-}50\%$ , and  $\leq 35\%$  in respectively 71, 24 and 5% of  
6 cases. Revascularization was performed on patients with one and two vessels CAD using PCI  
7 in 84% of cases, and on patients with three vessels CAD using CABG in 59% of cases.

8

9 *CARDIOVASCULAR RISK FACTORS* (Table 2)

10 In comparison with the initial evaluation, the body mass index (BMI) and the waist size were  
11 unchanged one year after the CR stay. The weight tended to increase ( $78.5 \pm 13$  versus  $79.2 \pm$   
12  $13$  kg,  $P = .05$ ). Lipid balances showed a downward trend in LDL cholesterol ( $84.6 \pm 39$  vs  $79.4$   
13  $\pm 28$  mg / dL,  $P = .06$ ) and an increase (12%) in HDL cholesterol ( $44.4 \pm 13$  vs  $49.9 \pm 14$  mg /  
14 dL,  $P < .001$ ). Regarding the 38 smoking patients, 18 had stopped during the follow-up, but 9  
15 former smokers have resumed smoking.

16

17 *EXERCISE TESTING DATA*

18 Table 3 and Figure 2 summarize the ET data.

19 In comparison with ET1, the maximum workload increased by  $29\% \pm 18$  ( $P < .001$ ) after CR  
20 and further increased by  $5\% \pm 15$  ( $P < .01$ ) one year after CR.

21 Considering their maximal weight-indexed workload (watts/kg) and CRF (estimated METs),  
22 one year after the end of CR, 163 patients (63%) improved or maintained it ( $ET3 \geq ET2$ ), 73  
23 (28%) decreased it ( $ET1 < ET3 < ET2$ ) and 23 (9%) lost the objective ( $ET3 \leq ET1$ ) benefit of  
24 CR.

1 The average CRF gain observed after the CR program was  $1.1 \pm 0.7$  METs ( $22.5 \pm 15$  %) and  
2 1-year after  $1.3 \pm 1.1$  METs ( $26.4 \pm 23$  %) (Table 3).

3 Table 4 shows that while the absolute gain in watts or METs was similar regardless of the initial  
4 CRF, percent improvement increased with decreasing CRF.

5 Resting heart rate (HR) decreased between pre-CR and post-CR with no additional modification  
6 one year later. Peak HR and heart rate reserve (HRR; peak HR-resting HR) were improved  
7 between ET1 and ET2 ( $P < .01$ ) as well as between ET2 and ET3 ( $P < .01$ ).

8 The training volume during CR stay was moderately correlated with the post-rehabilitation  
9 workload improvement ( $r = 0.24$ ,  $P < .001$ ), but no correlation was found after one year ( $P =$   
10  $.92$ ).

11

## 12 *SPECIFIC POPULATIONS*

13 The diabetic patients ( $n = 47$ ) presented a lower CRF ( $4.7 \pm 1.1$  versus  $5.4 \pm 1.4$  METs,  $P <$   
14  $.001$ ) and a lower workload improvement post-CR ( $26 \pm 31$  vs.  $30 \pm 20\%$ ,  $P < .03$ ) than the non-  
15 diabetic population. One year after CR, no difference was noted ( $3.2 \pm 13$  vs.  $4.8 \pm 15\%$ ,  $P =$   
16  $.62$ ). Their HDL-cholesterol blood value did not significantly increase in the follow-up post CR  
17 ( $44.5 \pm 14$  vs.  $48.4 \pm 16$  mg / dL,  $P = .08$ ).

18 One year later, non-weaned smokers ( $n = 20$ ), although younger ( $52 \pm 7$  versus  $62 \pm 10$  years,  
19  $P < .001$ ), decreased their workload ( $-0.06 \pm 0.13\%$  versus  $0.06 \pm 0.16\%$  for non-smokers and  
20  $0.06 \pm 0.14\%$  for weaned smokers,  $P < .004$ ). Their HDL-cholesterol blood value did not  
21 increase one year post CR ( $47.8 \pm 11$  versus  $45.6 \pm 13$  mg / dL,  $P = .41$ ).

22 No correlation was found between age, gender, BMI, presence of hypertension or dyslipidemia,  
23 and change in CRF one year post CR.

24

## 25 *OUTPATIENTS AND INPATIENTS*



1 The outpatients' CRF (n = 133) was higher than that of inpatients (n = 126), respectively  $5.4 \pm$   
2  $1.4$  vs.  $5.1 \pm 1.3$  METs ( $P < .002$ ) before the CR program, and  $6.7 \pm 1.6$  vs.  $6.1 \pm 1.5$  METs ( $P$   
3  $< .001$ ) at the end of the CR program. Improvement was also more significant,  $25 \pm 17$  vs.  $20$   
4  $\pm 12\%$  ( $P < .004$ ) for inpatients. After one year, the CRF was similar ( $6.7 \pm 1.7$  vs.  $6.5 \pm 1.7$   
5 METs ( $P = .18$ ) in both groups.

6

#### 7 *FOLLOW-UP*

8 During the follow-up, 38 patients (15%) were hospitalized, including 13 (5%) in cardiology.  
9 Five patients (1.9%) were revascularized including 2 ACS (0.7%), 1 atrial flutter ablation, 3  
10 cardiac defibrillator and 2 pace-maker implantations.

11

#### 12 **DISCUSSION**

13

14 This study analyses the early and medium-term (1 year) benefits of a CR program carried out  
15 in real life in French CR centers (in and outpatients) on the maximum workload and on the  
16 CRF of CAD patients. The global CRF gain observed and maintained after one year was 1.3  
17 METs, which is consistent.

18 The design of our study, which made sure to use the same protocol during the 3 exercise tests,  
19 and the fact that they were all carried out with unchanged individual medication, allowed a  
20 reliable comparison of the results observed during these three tests.

21 The CRF improvement was slightly lower than the average value of 1.5 METs reported in a  
22 recent meta-analysis<sup>17</sup>. The small discrepancy could be explained by the fact that the meta-  
23 analysis concerned outpatients and that their CRFs were evaluated on a treadmill. Moreover,  
24 the number of sessions was most often 36 during a 12 week duration. In our study, we also  
25 noted that outpatients benefited from a larger volume of training than inpatients, and presented

1 higher CRF improvement during the CR program. However, this benefit disappeared one year  
2 after the CR program. The CRF improvement we observed one-year post CR is in accordance  
3 with previous results observed with specific studies<sup>18,19</sup>. Moreover, our results are consistent  
4 with those of the SAINTEX multicenter study comparing continuous training versus interval-  
5 training, which found a similar CRF stability one year after the CR program, as well as with the  
6 EU-CaRE register in older patients<sup>20,21</sup>.

7 The CRF improvement observed in our CAD patients is valuable because of its previously  
8 proven prognostic value<sup>9</sup>. The highest observed CRF improvement, after the CR stay and  
9 maintained one year thereafter, concerning patients with the lower basal CRF value, suggests a  
10 greater survival in these high-risk CAD patients<sup>22,23</sup>.

11 Globally, the prognosis for CAD and diabetic patients is improved with the CR program<sup>24</sup>.  
12 However, data are conflicting concerning the benefit level of physical training in these patients.  
13 The gain value reported by other studies was less than, or similar<sup>25,26,27</sup> to our study.

14 Improvement in CRF in active smoking CAD patients was also less than that in non-smokers.  
15 This is consistent with the deleterious consequences of active smoking on CRF<sup>28</sup>. Smokers  
16 must always be encouraged to undertake regular physical training although evidence of benefit  
17 on smoking cessation remains weak<sup>29</sup>.

18 A North-American study has reported a decrease in PA in a CAD population two months after  
19 their hospitalization<sup>30</sup>. Therapeutic patient education aims at teaching patients how to reinforce  
20 their objectives by acting on all risk factors and to increase the level of their PA<sup>7</sup>. Nevertheless,  
21 therapeutic education alone does not seem effective enough<sup>31</sup>.

22 Data from PA self-questionnaires should be interpreted with caution because of the frequent  
23 overestimation reported, hence the choice in this study to measure the exercise capacity by a  
24 test<sup>32</sup>. Furthermore, many studies confirmed that the maintenance of a PA during phase III  
25 rehabilitation improved the CAD patient's survival rate<sup>33,34</sup>.

1 Long term improvement of individual CRF is the main goal of the CR and should be considered  
2 as the major prognostic factor. This would be best achieved with an individually adapted and  
3 supervised physical training program, and associated with patient education provided by a  
4 multi-professional team. Moreover, we could speculate that the duration of the CR program  
5 should be adapted to the initial CRF value, with more physical training for patients with lower  
6 CRF values, and more education for patients with higher CRF values.

7

#### 8 *INTERESTS AND LIMITS OF THE STUDY*

9 This study concerned the real-life typical cardiac rehabilitation. It could be reproduced in other  
10 countries presenting different rehabilitation modalities. Multicenter data also provided a real  
11 insight into the current situation.

12 Patients with severe heart failure or who had undergone recent non-coronary surgery were not  
13 included. Moreover, the results of this study concerned patients who agreed to participate in the  
14 protocol. The included population was relatively young and with a very small participation of  
15 females<sup>35</sup>.

16 No control group was included, however spontaneously, non-rehabilitated CAD patients do not  
17 practice any PA after an ACS due to habits or fear<sup>30,36</sup>.

18 The CRF has been evaluated with the FRIEND formula. Despite the fact that cardiopulmonary  
19 exercise tests were not performed, patients with beta-blockers (90 to 95%) achieved the  
20 predicted maximal heart rate according to the Brawner formula for patients with beta-blockers  
21  $(164 - 0.7 \times \text{age})^{37}$ .

22 During the follow-up period, the PA level evaluation had not been considered because of the  
23 difficulties encountered in estimating real PA. More precise evaluation with activity sensors  
24 would have been useful. In accordance with the data of the EU-CaRE study, the increase in

1 HDL-cholesterol that we observed was consistent with PA maintenance and reinforces the  
2 results of our study<sup>21,38</sup>.

3 Our study did not require identical training protocols, only the number of sessions and their  
4 duration were collected. Thus, it was not possible to compare continuous endurance with  
5 interval training. However, the SAINTEX study did not find any difference between these  
6 modalities one year after the physical training period<sup>22</sup>.

7 Lastly, 12-month follow-up does not predict the long-term effect of CR on maintenance of CRF  
8 and control of risk factors<sup>39</sup>.

9 Our study did not include specific follow-up and could be used as reference for French CR  
10 middle term results. Thus, we could not evaluate the patient's leisure-time PA. This reflects the  
11 current reality, and our results could probably be improved with an adapted intervention (mobile  
12 messages, motivational interviews, psychosocial support ...), which are good topics for further  
13 studies<sup>40</sup>.

14

## 15 **CONCLUSION**

16

17 In a French coronary patient cohort, among completers who agreed to enroll in this study, the  
18 improvement in functional capacity observed after a standard cardiac rehabilitation was  
19 maintained one year after the end of the stay for most coronary patients, without any specific  
20 management during the follow-up.

21

## 22 **AUTHOR CONTRIBUTION**

23 BP, SK, BPV, SC, MCI, ACS and FC contributed to conception and design of the study. BP,  
24 SK, CR, EM, HK, AT contributed to acquisition of data. BP, MCI, ACS and FC drafted the

1 manuscript, SK, CR, EM, HK, AT, MCI, ACS and FC critically revised the manuscript. All  
2 authors have read and approved of the manuscript.

3

#### 4 **DECLARATION OF CONFLICTING INTERESTS**

5 The authors declared no potential conflicts of interest with respect to the research, authorship,  
6 and/or publication of this article.

7

#### 8 **ACKNOWLEDGEMENTS**

9 We warmly thank the investigators of the following participating centers: Dr Sophie Lamoureux  
10 (Lyon), Dr. Julie Darchis (Machecoul), Dr Bénédicte Patois-Vergès (Dijon), Dr Lamia Tartière  
11 (Hyères), Dr Véronique Berder (Rennes), Dr Sonia Corone (Bligny), Dr. Bernard Pierre (Marcy  
12 l'Etoile), Dr. Anne-Lise Gugenheim (Corbie), Dr Véronique Gebuhrer (Villeurbanne), Dr Jean-  
13 Michel Guy (Saint-Priest en Jarez), Dr Nataliya Hrynychynshyn (Pontoise), Dr Eric Gobin  
14 (Noirmont) and Dr. Charlotte Mestrallet (Rumilly). Special thanks to Nathaniel Symes for his  
15 proof-reading.

16

#### 17 **FUNDING**

18 This research did not receive any specific grant from funding agencies in the public,  
19 commercial, or not-for-profit sectors.

20

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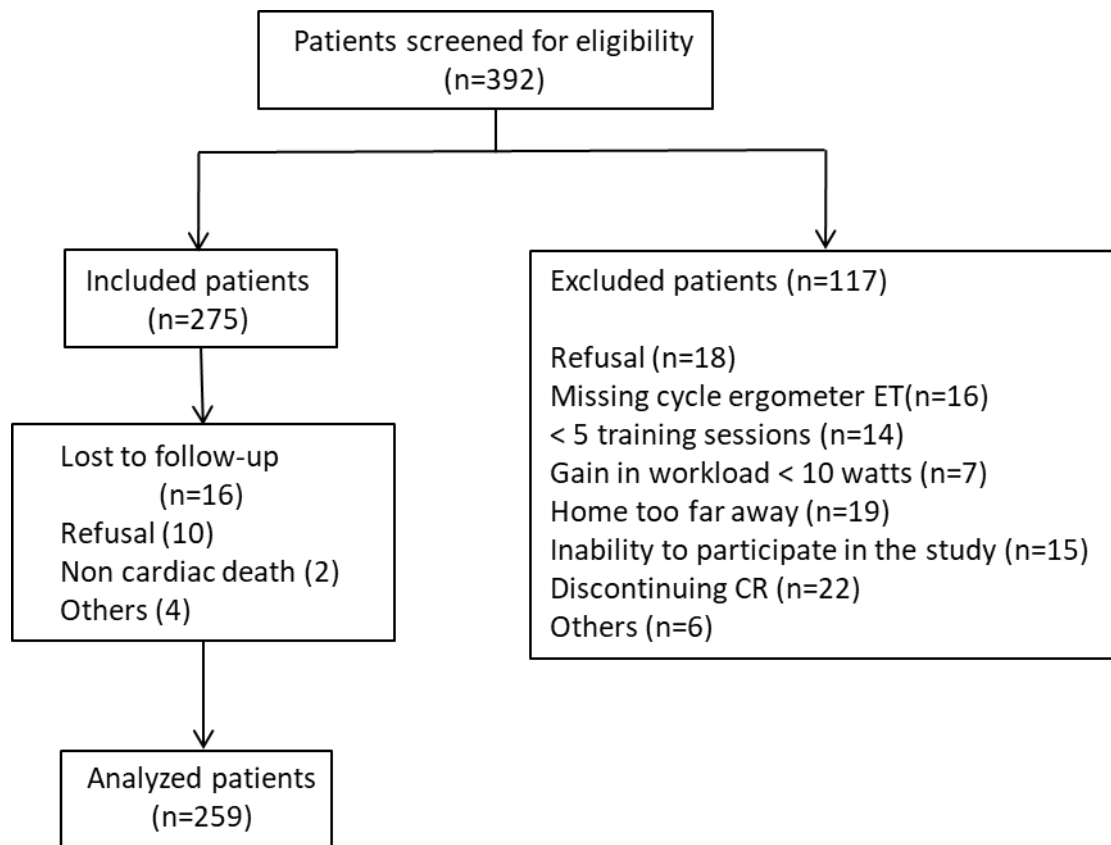


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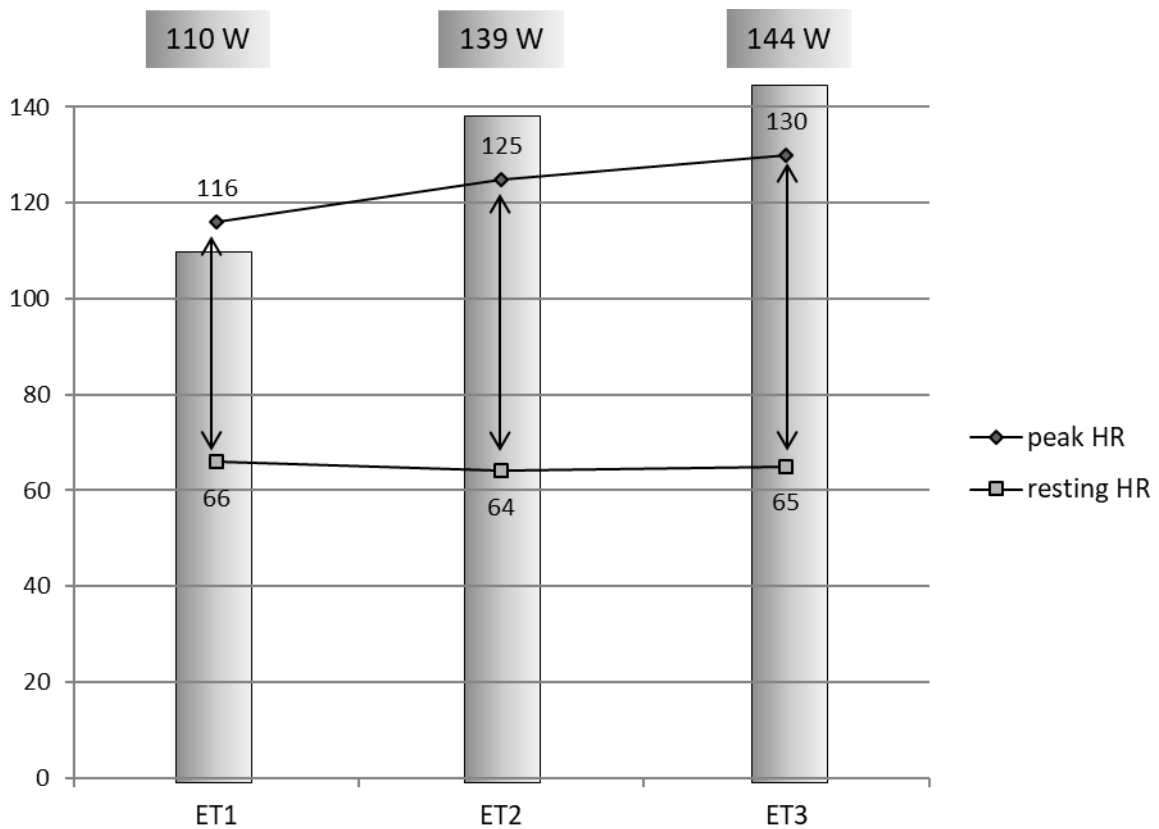
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**Figure1.** Flow diagram of study participants. ET indicates exercise test; CR, cardiac rehabilitation

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3 **Figure 2.** Evolution of the exercise tests (ET): the columns indicate the workloads at the first  
4 ET(ET1), the final ET (ET2) and the one-year ET (ET3); peak HR increased, resting HR were  
5 stable, HR reserve (HRR) increased (arrows); see details on table 3.

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1	<b>Table 1</b>	Baseline data (n = 259)	
2	<i>Demographic data</i>		
3	Men		230 (89)
4	Age, yr		60 ± 10
5			
6	<i>Pathology</i>		
7	ACS	STEMI	149 (58)
8		NSTEMI	51 (20)
9		Anterior	81 (31)
10		Inferior	74 (29)
11		Lateral	16 (6)
12		Undetermined	29 (11)
13	LVEF, %		55 ± 9
14	Coronary angiography		
15		Single-vessel	122 (47)
16		Two-vessel	67 (26)
17		Three-vessel	70 (27)
18	Coronary revascularization		
19		PCI	189 (73)
20		CABG	72 (28)
21		Complete	211 (81)
22		None	5 (2)

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24 Data are expressed as number (%), or mean ± standard deviation

25 Abbreviations: ACS, Acute Coronary Syndrome; CABG: Coronary Artery By-pass Graft;

26 LVEF: Left Ventricular Ejection Fraction; PCI: Percutaneous Coronary Intervention;

27 NSTEMI: Non-ST segment Elevation Myocardial Infarction; STEMI: ST segment Elevation

28 Myocardial Infarction.

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	Beginning of CR	1-year post CR	P Value
	n=259	n=259	
BMI, kg/m <sup>2</sup>	26.4 ± 3.7	26.7 ± 3.7	.06
Waist size, cm	97 ± 11	97 ± 11	.19
Smoking			
<i>Never</i>	100 (40)	100 (40)	.46
<i>Former</i>	119 (48)	128 (51)	
<i>Current</i>	38 (15)	29 (12)	
High Blood Pressure	115 (44)	NA	
Diabetes	47 (18)	NA	
Hypercholesterolemia	153 (59)	NA	
LDL Cholesterol, mg/dL	85 ± 39	79 ± 28	.06
HDL Cholesterol, mg/dL	44 ± 13	50 ± 14	< .001
Family premature CHD	97 (37)	NA	

Data are expressed as number (%), or mean ± standard deviation  
Abbreviations: BMI, Body Mass Index; CHD, Coronary Heart Disease; CR, cardiac  
rehabilitation; NA, not adapted;

1 **Table 3** Results of the exercise testing

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	ET1	ET2	<i>P</i> Value ET1 vs. ET2	ET3	<i>P</i> Value ET2 vs.ET3
	n = 259	n = 259		n = 259	
Resting HR, bpm	66 ± 13	64 ± 10	<.008	65 ± 11	.22
Peak HR, bpm	116 ± 19	125 ± 18	<.001	130 ± 19	<.001
HRR, bpm	50 ± 19	61 ± 18	<.001	65 ± 19	<.001
Workload, W	110 ± 37	139 ± 43	<.001	144 ± 46	<.001
Relative workload, W/kg	1.41 ± 0.46	1.78 ± 0.53	<.001	1.83 ± 0.56	<.003
Estimated CRF, MET	5.3 ± 1.4	6.4 ± 1.6	<.001	6.6 ± 1.7	<.002

14  
15 Data are expressed as number (%) or mean ± standard deviation

16 Abbreviations: CRF, cardiorespiratory fitness; ET1, exercise test before training program;  
17 ET2, exercise test at the end of training program; ET3, exercise test one year after the end of  
18 training program; HR, Heart Rate; bpm, beat per minute; HRR, Heart Rate Reserve; MET,  
19 Metabolic Equivalent of the Task.  
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