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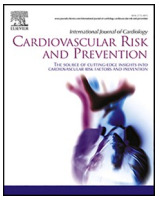

Effectiveness of home-rehabilitation in patients after an acute coronary syndrome and myocardial revascularization

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ABSTRACT

Physical activity is a mainstay (class IA) of rehabilitation programme after an acute coronary syndrome, but less than 40% of patients is physically active at one year. Home-rehabilitation, initially designed to manage the increasing number of patients in rehabilitation programmes, could result in a better strategy to increase adherence and persistence to physical activity.

Objectives: To test such hypothesis, At Cardiac Rehabilitation Centre (Institute of Physical Medicine and Rehabilitation, Udine, Italy), physical activity adherence was compared between patients treated with a standard in-office rehabilitation programme and a cohort where home rehabilitation programme was added.

Methods: From February 2017 to February 2019, 372 patients after an acute coronary syndrome (72 were excluded according to study criteria) were included, 193 patients in standard rehabilitation and 179 in home rehabilitation. At the end of follow-up, patients of both groups were called on the telephone to collect physical activity items according to a standardized questionnaire.

Results: At a medium follow-up of 30.1 months, there are more physically active patients in home rehabilitation than in standard, respectively 139 vs 108 patients (77,1% vs. 56%, $p < 0,0001$).

At multivariate analysis, including age, gender, and rehabilitation model, the probability to be fully physically active at the end of the rehabilitation programme, is 3 times higher (OR 3.0 CI 1,9-6,0 $p < 0,0001$) for home rehabilitation programme compared to standard one.

Conclusions: Home rehabilitation, when applied to selected populations, resulted in a feasible and effective strategy to promote long term physical activity in secondary prevention after an acute coronary syndrome.

1. Introduction

Atherosclerotic disease is the leading cause of mortality in Western but also in developing countries [1]. Incidence is associated to the level of risk factors such as cigarette smoking, LDL-C levels, hypertension, diabetes, overweight and obesity, and sedentary lifestyle [1].

Mild and multiple risk factor reduction is an effective primary prevention tool for the general population [2], whereas an intensive reduction is also highly effective to reduce the progression of disease in high-risk subject and in overt patients (class IA ESC guidelines).

Physical activity (PA) on regular basis (daily 30 min of mild intensity aerobic activity) is highly effective in reducing the risk of disease progression, resulting in an increase in overall survival and QoL (Quality of Life), reduced non-fatal cerebro-vascular events. For all these reasons, it should be considered by patients equivalent to a "tablet" [3,4]. Its effectiveness, however, is largely reduced by the poor long-term persistence. Adherence to this guideline, persistently in the last decades, is scarce. In Euroaspire V survey, only one third of patients reach the PA recommended goal [5].

In standard-of-care, PA promotion and reinforce is limited to the period of rehabilitation participation, usually limited to few weeks/months. In selected population (i.e., patient afferent to specialized Rehabilitation Centre), PA adherence at one year is better but less than optimal [6].

Strategies to effectively enhance PA in all-day life after the completion of SR programme are lacking in guidelines.

Home rehabilitation (HR) is complementary to in-office standard rehabilitation (SR), in a selected population of clinically stable patients

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at low and intermediate risk factors risk, with similar improvement of functional physical capacity [7]. HR could represent a strategy to increase the adherence and persistence to PA when added to standard rehabilitation.

2. Aim of the study

Aim of the study is to investigate whether HR, added after completion of SR, can increase the persistence of PA at a long-term follow-up.

3. Materials and methods

At Cardiac Rehabilitation Centre (IMFR, Institute of Physical Medicine and Rehabilitation, Udine, Italy), serving an overall population of approximately 530,000 inhabitants, a cohort of patients were entered a programme of HR after completion of SR. Physical activity adherence was compared between HR cohort and a standard rehabilitation cohort (SR).

3.1. Standard rehabilitation programme

SR consisted of a personalised outpatient clinical calendar; a standardized educational programme (4 lessons of focused topics with nurse counselling), and a minimum of 15 gym sessions.

3.2. Home rehabilitation

After an acute coronary syndrome (ACS), patients were offered to enter a HR programme when judged suitable according to physical status (i.e., absence of invalidating comorbidities), home facilities (i.e., phone at home), risk profile. Exclusion criteria in both cohorts were: age less than 18 years, participating in less than 10 gym lessons, less than 50% response to HR phone call, self-declaring physically not adherence to HR programme, onset of invalidating disability at follow-up, refusal of informed consent.

HR programme consisted in ad-hoc audio-visual media and specific counselling aimed at prosecuting exercise at home. Scheduled PA consisted in daily walk at a tailored training heart rate for 30 min, and free body exercise (according to audio-visual media provided) for 40 min at least three times a week. Patients receive 4 phone call (20 min each) to reinforce the adherence to healthy lifestyle life and physical activity. A typical HR programme takes 4 weeks months.

3.3. Physical activity at follow-up

At the end of follow-up, patients of both groups were called on the telephone (between May and August 2020) to collect PA items according to a standardized questionnaire (PASSI Project, National Health System [8]. According to PASSI Project patients were classified as:

- physically active
  either with a job requiring a vigorous physical effort such as farmer, bricklayer, etc., or is compliant with WHO criteria (moderate activity for at least 30 min 5 days a week or heavy activity for at least 30 min and 3 days a week).
- partially active
  subject who does not carry out a physical heavy work, but is somehow active in free time, but less than WHO recommendation
- sedentary
  not employed in heavy job with no physical activity during free time.

All patients participating to a rehabilitation programme signed the informed consent, inclusive of phone call follow-up. Specific study consent was administered at first phone contact. The study was approved by local Ethical Committee (CEUR-2020-OS-047, 10/03/2020).

3.4. Statistics

Assuming that 60% of patients who enter a rehabilitation programme is physically active after one year and that the proportion of physically active patients could increase to 75% in case of HR, with a 1:1 ratio of patients participating to a traditional rehabilitation programme and to HR, accepting a 5% alpha error and a 20% beta error, we estimated that the minimum number of patients to enrol in the study was 308 (158 in each group). Considering that the information provided by some patients could be incomplete, and that some patients could drop out of study before the end of follow-up, we decided to enrol an additional 20% of subjects. Thus, the final sample size for the study was 370.

For this study, we collected information on demographic and social characteristics of patients, on their health profile and on characteristics of the rehabilitation programme.

The distribution of the variables was presented through mean values and standard deviations in case of normally distributed continuous variables, through the median and interquartile range (IQR) in case of non-normally distributed continuous variables, and through percentages in case of categorical variables.

The statistical significance of differences between the groups of patients was assessed through the *t*-test, the Wilcoxon test, or the chi-square test, respectively. *P*-values<0.05 were considered statistically significant.

Multivariate logistic regression models were built to assess the association between being fully physically active and type of programme, adjusting for the potentially confounding effect of age and sex of the patient. Multinomial ordinal regression was used to assess the likelihood of being fully physically active and partially physically active vs sedentary at the one-year follow-up, adjusting for age and sex of patient. The odds ratio (OR) and 95% Confidence Intervals (95%CI) were calculated.

4. Results

From February 2017 to February 2019, 444 patients after an ACS were admitted to a rehabilitation programme at IMFR. Seventy-two were excluded according to study criteria. A total of 372 pts was finally included, 179 in HR cohort, 193 in SR cohort (Table 1).

Patients were followed for a mean of 30.8 months (median 31, IQR 24–38 months), with no difference between two groups ($p = 0.46$).

The most relevant difference between HR and SR cohorts is the mean age, being the latter cohort 9 years older (Table 1 and Fig. 1). In the SR cohort, female gender is more represented, and actively employed patients (with a more sedentary job) are 13% vs 60% in HR cohort. Average schooling is slightly higher in HR cohort. Among clinical characteristics, hypertension is more represented in standard-of-care cohort, as well as cardiac surgery.

Association among clinical characteristics and persistence of PA at follow-up is reported in Table 2, for the whole population.

Male gender and a higher education level are associated with more physical activity at follow-up. Obesity, sedentary at workplace or to be unemployed are all factors associated with a sedentary lifestyle. Risk factors (beside hypertension), comorbidities, e left ventricular function, are roughly even distributed in two cohort, and seem not to affect physical activity.

Physically active patients, at a medium follow-up of 30.1 month, are more present in HR compared to SR cohort, respectively 139 pts vs 108 pts (77.1% vs. 56.0%, $p < 0.0001$). In both groups, physical activity is carried out mostly alone, although in HR the presence of a mate is more frequent (8.9% vs 2.6%), likely because prompted to do so by training personnel during phone calls.

At multivariate analysis, including age, gender and rehabilitation model (HR, vs SR), the probability to be fully physically active at the end

Table 1
Baseline characteristics of cohorts (number expresses percentage).

	SR cohort	HR cohort	p
	n = 193	N = 179	
Age (years, mean/median)	69.8/70	60.7/61	<0.0001
Female gender	18.1	8.9	0.001
Living habitat			
- Town/City	37.3	33	ns
- Rural area with facilities for safe walking	61.7	64.2	
- Rural area w/o facilities for safe walking	1.0	0	
- Mountain area	0	2.8	
School			
- Primary	15.5	6.7	0.02
- Middle	32.1	28.5	
- High school	39.3	52.5	
- University	12.9	12.3	
Physical activity at job site			
- Sedentary	6.2	17.9	<0.0001
- Moderate	4.7	37.4	
- Heavy	0.5	9.0	
- Retired	87.0	39.7	
Risk and clinical factors			
- Hypertension	72	60.3	0.01
- Diabetes	23.3	21.2	0.6
- Smoking	67.4	69.3	0.13
- Obesity	36.2	31.3	0.3
- BPCO (n)	4	0	0.3
- Cardiac surgery	42.5	29.0	0.03
- PCI	37.5	71.0	
- EF > 50%	92.2	91.6	ns
- EF 40–50%	6.2	8.4	
- EF < 40%	1.6	0	
Physical activity			
- With the dog	12.4	15.1	0.01
- With a mate	2.6	8.9	
- Alone	85.0	76.0	

of the rehabilitation programme, is 3 times higher (OR 3.0 CI 1.9-6.0 p < 0.0001) for home rehabilitation programme compared to standard one (Fig. 2).

A reduced likelihood of being fully physically active with borderline statistical significance was observed among female patients (p = 0.07, 95%CI 0.30–1.05). For each increasing year of age, there was a 3% increase in the likelihood of being physically active at the end of follow-up p = 0.06, 95% CI 0–7%).

Multinomial ordinal regression showed that HR increases the odds to be fully physically active by 8 times compared to sedentary lifestyle (p = 0.0003) and the odds to be moderately active by 3 times compared to sedentary (p = 0.07).

5. Discussion

Physical activity on a regular basis is highly effective in reducing the risk of disease progression and non-fatal cerebro-vascular events, resulting in an increase in overall survival and QoL. Its effectiveness, however, is largely reduced by the poor long-term persistence [3,4].

In our cohort, at a mean 2.5-year follow-up, 56% of patients prosecuted physical activity (according to WHO definition) after participation to a standard in-office programme. However, when home rehabilitation was added to, the proportion of active patients significantly raised up to 77% (plus 37.5%) confirming the initial hypothesis that favouring physical activity also at home significantly increase overall long-term adherence. In our study, home-rehabilitation independently increases the odds to be fully physically active by 8 times compared to sedentary lifestyle and the odds to be moderately active by 3 times compared to sedentary. Factors leading to a reduced physical activity at follow-up in the standard in-office rehabilitation group are the older age (10 years on average), a higher prevalence of related comorbidities, the larger prevalence of cardiac surgery compared to percutaneous treatment, and

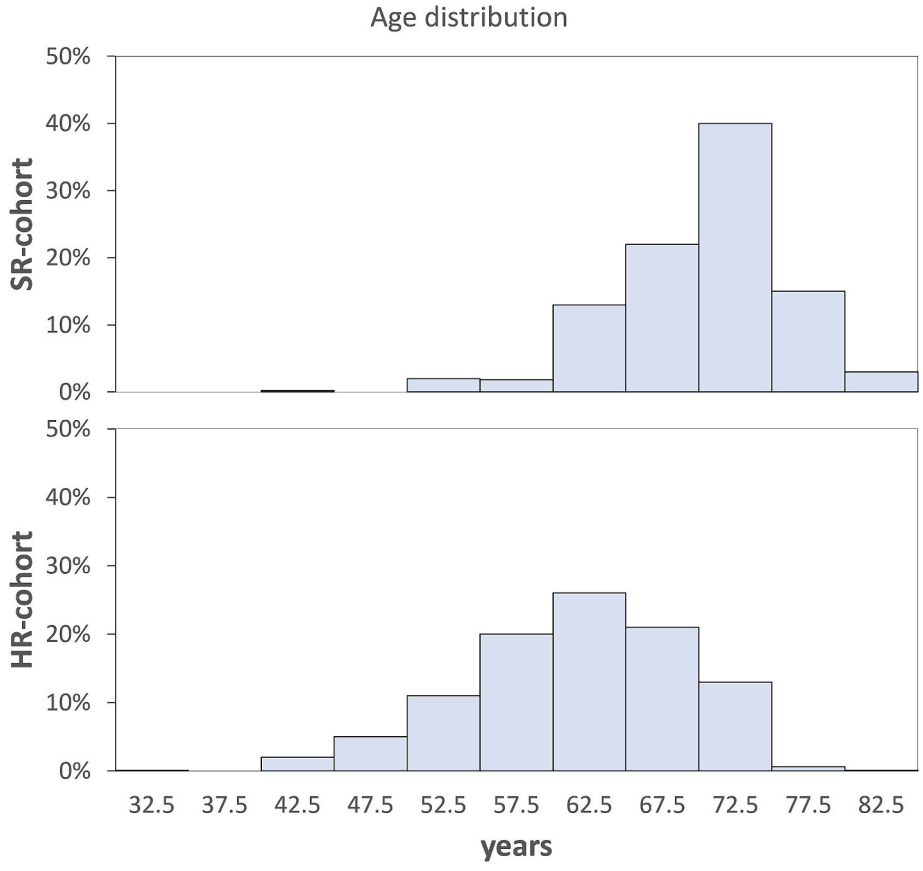

Fig. 1. Age distribution in HR-Cohort and SR-Cohort.

Table 2
Clinical characteristic conditioning persistence of physical activity at follow-up for the whole population (univariate analysis).

	Physical Active	p
	N (%)	
Age (years)		n.s.
- ≥65	145 (65.6)	
- <65	101 (66.9)	
Gender		0.006
- female	25 (49.0)	
- male	221 (68.9)	
Living habitat		
- Town/City	81 (61.8)	n.s.
- Rural area with facilities for safe walking	161 (68.8)	
- Rural area w/o facilities for safe walking	0 (0)	
- Mountain area	4 (80)	
School		
- Primary	20 (47.6)	0.014
- Middle	77 (68.1)	
- High school	122 (71.8)	
- University	27 (57.4)	
Physical activity at job site		
- Unemployed	2 (66.7)	
- Sedentary	20 (45.5)	<0.006
- Moderate	54 (71.1)	
- Heavy	10 (100)	
- Retired	160 (70.0)	
Hypertension		n.s.
- Yes	159 (64.4)	
- No	87 (69.6)	
Diabetes		n.s.
- yes	54 (65.1)	
- no	192 (66.4)	
Smoking (status at admission)		n.s.
- Active (after discharge)	16 (55.2)	
- Ex (>1 year)	95 (65.5)	
- Ex (at discharge)	55 (68.8)	
- Never	80 (67.8)	
Obesity (BMI ≥ 30)		0.016
- yes	73 (57.9)	
- no	173 (70.3)	
COPD		n.s.
- Present	2 (50)	
- Absent	2 (50)	
Cardiac surgery		n.s.
Myocardial revascularization		
- PCI	147 (67.7)	
- CABG	79 (64.7)	
- CABG + valve	10 (83.3	
- Medical Therapy	10 (47.6)	
Left Ventricle Ejection Fraction		n.s.
- > 50%	224 (65.5)	
- 40%–50%	20 (74.1)	
- < 40%	2 (66.7)	
Physical activity		
- With the dog	34 (66.7)	n.s.
- With a mate	16 (76.2)	
- Alone	196 (65.3)	
Home rehabilitation		<0.0001
- Yes	138 (77.1)	
- No	108 (56.0)	

Legend. Within each variable, different categories (percentages) were compared.
Abbreviation. BMI: body mass index; COPD: chronic obstructive pulmonary disease; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; n.s.: statistically not significant.

female gender. Older age led to more PA at follow-up, probably due to a selection bias of "fit" elderly and with more free time after retirement.

Home-rehabilitation developed to let a wider patients' participation to rehabilitation programme. It has been also proposed as an alternative to standard rehabilitation in stable patient at low and intermediate residual cardiovascular risk, resulting equivalent in improving functional capacity in several studies [7]. HR carries some disadvantages as well. Physical exercise is generally not supervised and potentially less intense; less social interaction, lack of monitoring and communication between personnel and patient, more concerns when proposed to high-risk patients.

Due to its feasibility, HR has the potential to improve participation and adherence to rehabilitation programme, but at present results are discordant. Specific guidelines and protocols for HR are lacking, although ACC/AHA in guidelines rehabilitation update, include home base rehabilitation as an alternative for low-risk patients [9].

In 2014, a metanalysis of 26 randomized controlled trials comparing standard rehabilitation with a programme of a nurse phone counselling, reported a significant reduction of hospital admission (−38%) and levels of anxiety and depression. Smoke cessation increased by 32%. Among cardiovascular risk factors, nurse intervention resulted in a better blood pressure control, and was neutral respect to LDL and overall mortality [10]. Some models show the efficacy of a hybrid approach merging initial on-site training sessions followed by HR, implemented with nurse counselling and reinforcement [11].

Information and Computer Technology applied to telemedicine allowed home rehabilitation to be attractive and feasible. Korean researcher, pointing at monitoring and guide the training level, developed a rehabilitation programme based on a smartphone as the unique monitoring system. Through a dedicated app, the level of physical exercise and heart rate are monitored in real time and compared to the tailored target. During exercise the App guides patients' training level with vocal advice and adapting intensity to heart rate and motion. A self-administered questionnaire concerning the eventual symptoms onset (e.g., dyspnoea, angina and claudicatio) complete a final report [12].

Mobile devices are a resource for promoting heath lifestyle, cardiovascular prevention, and rehabilitation, due their large public acceptance and efficacy. Physicians should be more aware of it and use them also for patient self-management of risk factors and monitoring and as an aid to translate into daily routine (home, workplace) theory acquired in healthcare environment [11,13].

In United Kingdome HR is implemented by a NHS the *Heart Manual Program*, a NHS service providing evidence-based programmes for individuals recovering from myocardial infarction, revascularization, and stroke. Programmes are facilitated (via phone calls or app chat) by specially trained clinicians worldwide to individually tailor the programme and support patients' understanding and management of their condition [11].

In a Canadian model HR is implemented over a 6 moths period intercalated every 2 weeks by phone calls to monitor adherence, to tune physical load, and reinforce educational support.

In the United States it is not covered by reimbursement, with the relevant exception of MULTIFIT, a nurse-based home-rehabilitation and tele-monitoring programme (with smart devices) implemented by Kaiser Permanente Northern California. MULTIFIT, starting during hospital stay end prosecuted during the next 6 month [11]. Conversely, in U.S.A., HR is offered in non-clinical setting, such as public and private social and fitness club, public parks, all facilities to overcome geographic, logistic, and economic barriers.

China developed prevention and rehabilitation programs as mobile health -*mHealth*-with encouraging results in terms of adherence, smoke cessation, weight loss, physical activity, and adherence to lifestyle advice. Communication to participants used multi-media, starting with SMS, and ending with social media, with better results, compared to standard of care, in terms of functional recovery, self-consciousness of the disease, and adherence to therapy [14].

In Italy, Centro Maugeri holds the longest experience in HR, having implemented in 1998 its first tele-monitoring system based and phone calls for chronic care (COPD, heart failure, post CABG, post ICTUS, ALS). The 15-years centre experience has been recently published [15]. From 2000 to 2015, 1635 patients with chronic disease (heart failure and COPD represented 80% of pathologies) were followed with a tailored telemedicine program. In heart failure patients, readmission rate was reduced by 44%, relapse by 50%, with a 24% reduction in costs, when

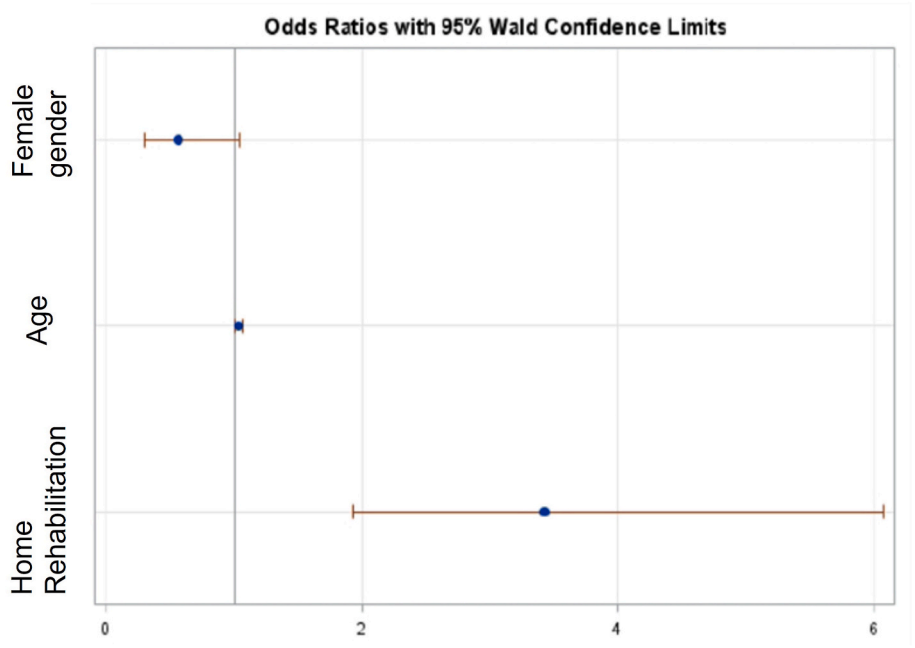

Fig. 2. Physical state (not active vs. active) at multivariate analysis.

compared to the standard care model. In post CABG patients, Authors showed the feasibility of HR and the non-inferiority compared to hospital rehabilitation.

5.1. Limitations

The main limitation of the study is its observational design and the comparison of different cohorts of patients with different therapeutic strategies. A third cohort of patients with similar demographic and clinical characteristics of HR, but not candidate to home rehabilitation programme could have confirmed that the latter is associated with physical persistence. Both these limitations are at least partly overcome by multivariate analysis. However, in case of studies comparing different interventional strategies, well conducted registries (even retrospective) can offer results more transferable into daily practice. This because the lack of randomization permitted to reproduce the selection of suitable patients (in our case, suitable for HR) fitting the interventional arm.

A second limitation, although general in such type of studies, is the difficulty of physical activity quantification, when the latter is not scheduled on a daily or weekly basis but let to patient's free scheme. Besides that, exertion level is more linked to fatigue than to an objective intensity. To overcome this drawback patients were asked in depth according to standardized and validated questions of national PASSI project. Furthermore, inter observer interpretation variability has been abolished by the single phone caller and the narrow time lapse of the study (3 months among initial and last phone calls).

6. Conclusions

According to our study, home-rehabilitation is a simple and feasible tool to increase mid-term physical activity adherence when compared to standard in-office rehabilitation programme in patients after an acute coronary syndrome.

Credit author statement

Marika Werren: Conceptualization, Methodology. Francesca Valent: Formal analysis, Writing – review & editing. Antonio Di Chiara: Writing – original draft, review and editing.

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