Original Article

Evaluating the Effectiveness of Home based versus Comprehensive Cardiac Rehabilitation on Mortality in Myocardial Infarction Survivors

Abstract

Background: Myocardial infarction (MI) is a health concern with different mortality rates even with advanced treatment. Home care is a new approach for monitoring and providing care to MI patients after discharge. This study aimed to evaluate the effectiveness of home based versus comprehensive cardiac rehabilitation recommendations on mortality among MI survivors. **Method:** This randomized clinical trial at Cardiac Rehabilitation Research Center, Isfahan, involved myocardial infarction survivors. Participants were divided into intervention (home based CR) and control (comprehensive CR) groups with a block randomization method. Mortality, returning to work, and rehospitalization rates of both groups were assessed and compared at 6, 12, and 60 months after MI. **Results:** Totally 259 participants were included in this study. Baseline variables were relatively similar in both groups. The odds of death in home care were 45% less than the control group (OR = 0.55, 95% CI: 0.21 – 1.45, $P = 0.229$), and the odds of death changed 1,09 times by increasing each year of patients (OR = 1.09, 95% CI: 1.01 – 1.18, $P = 0.027$). Also, returning to work was significantly higher in the intervention group during the 0–6-month period (intervention group = 99.08% vs. control group = 92.31% $P = 0.032$). **Conclusions:** The study found a 45% lower risk of death in the home based group, which was not statistically significant, possibly due to sample size limitations. However, the rate of returning to work activity was higher in the home based CR group. The home based method can be chosen as an alternative to comprehensive CR based on decision-making with the patient, specialists, and caregivers.

Keywords: *Cardiovascular diseases, home based cardiac rehabilitation, mortality rate, myocardial infarction, RCT*

Fereshteh Beheshti-nia[1], Masoumeh Sadeghi[2], Alireza Ansari-Moghaddam[3], Mahdi Mohammadi[3], Hassan Okati-Aliabad[3], Ghasem Yadegarfar[4,5]

[1]Department of Epidemiology and Biostatistics, School of Public Health, Isfahan University of Medical Sciences, Isfahan, Iran, [2]Cardiac Rehabilitation Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran, [3]Health Promotion Research Center, Zahedan University of Medical Sciences, Zahedan, Iran, [4]Heart Failure Research Center, Cardiovascular Research Institute, School of Public Health, Isfahan University of Medical Sciences, Isfahan, Iran, [5]Primary Community and Social Care, School of Medicine, Keele University, Keele, Staffordshire, UK

Address for correspondence:
Prof. Ghasem Yadegarfar, Department of Epidemiology and Biostatistics, School of Public Health, Isfahan University of Medical Sciences, Isfahan, Iran.
Primary Community and Social Care, School of Medicine, Keele University, Keele, Staffordshire, UK"
E-mail: yadegarfar@gmail.com.

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Introduction

Myocardial infarction (MI) is one of the cardiovascular disorders that is rising throughout the world.[1] According to a previous systematic review, the incidence of MI is 3.8%-9.5% until 2023[2] and the mortality rate was 5% to 30% in different countries.[3] Previous studies reported a high percentage (15.95%) of deaths occur before hospitalization in England,[4] and 11.7% of patients die in one year after an MI in Iran.[5,6] Mortality rates can be influenced by various factors, including the severity of the MI, comorbidities, quality of care, patient monitoring, and recovery processes.[7] Previous studies reported that the average hospitalization length after MI is under 10 days, and patients often excluded from active follow-up and monitoring.[8]

Home care is a modern, cost-effective method that provides recovery and monitoring services to patients at home.[9] Personalizing care in a familiar environment can increase patient satisfaction and quality of life, reducing stress and anxiety, and ultimately improving health outcomes.[10] In addition, home care can include efficient training, early recurrence diagnosis, management of side effects, and rehabilitation.[11,12] Previous studies showed that home care can improve physical activity levels, treatment consistency, and psychological health. Also, it can reduce negative health behaviors, such as smoking, as well as lower the recurrence of stroke and MI mortality.[12] Various factors, such as culture, type of disease, and quality of home care implementation, can affect the effectiveness of home care. This study aimed to evaluate the impact of home care compared to routine hospital care on mortality in MI survivors.

Methods

Study design and participants (population)

This randomized clinical trial (non-pharmacological) was conducted at Cardiac

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Rehabilitation Research Center of Cardiovascular Research Institute, Isfahan, in patients who survived myocardial infarction (MI). Participants were randomly allocated to an intervention group (home based cardiac rehabilitation (CR)) and a control group (Comprehensive CR) by block randomization method. Inclusion criteria included being over 18 years old and having a recent history of MI hospitalization. Exclusion criteria were a history of heart surgery, dementia or severe mental disorders, unstable cardiac angina, arrhythmias, language or verbal communication disorders, and inability to exercise or exercise prohibition due to illness.

Randomization and blinding

After participants were included, they were randomly assigned to two intervention groups or control groups. Block randomization was used to create 42 blocks of 6 cells and 2 blocks of 4 cells that patients were randomly assigned. The sequence of assigning participants to the blocks was also conducted by randomization. In addition, blinding was implemented for both data collectors and data analysts.

Intervention

The participants in the control group received comprehensive CR including a cardiac rehabilitation educational program, health recommendation (without supervision session), exercise test, and nutritional and psychological counseling sessions at the beginning, 3, and 12 months of the trial. Participants in the intervention group received routine rehabilitation and 4 supervised home-based cardiac rehabilitation, a customized physical activity program based on the baseline exercise test, and routine physician visits at the beginning, 10 days, 1 month, and 3 months after the first visit. Additionally, they had weekly telephone follow-ups, monthly smoking cessation sessions, psychological counseling, home visits by a trained nurse, and direct phone contacts to cardiologists in the occurrence of symptoms or difficulties.

Outcome assessment

The outcome of this study was assessing vital status (death/alive) in patients who survived myocardial infarction (MI) during 6, 12, and 60 months. The researcher used a checklist and used the interview approach (by telephone) to gather the data. Interviews were conducted with the living participant or with a deceased participant's relative. The researchers evaluated the death status of all patients in the study at 6, 12, and 60 months after the included time. The participant was labeled as a loss to follow up if they did not respond to three attempts of contacting them or if they did not consent to continue cooperating.

Statistical analysis

Frequency and percentage were used to describe qualitative data. Mean and standard deviation were used to examine quantitative data with normal distribution. The mean of the quantitative variables was compared between the two groups by using the *t*-test. The association between two qualitative variables is determined by the Chi-square test and Fisher's exact test. Also, the association between potential associated factors and the death outcome was determined by logistic regression. The STATAver 16 program was used to conduct all analyses. All analyses were concudet as two-tailed with a statistical significance level of less than 0.05.

Table 1: Comparison of baseline variables between the control and home care groups at the study initiation time

Variable	Control *n* (%)	Home care *n* (%)	Total *n* (%)	*P*
	128 (49.42)	131 (50.58)	259 (100)	
Sex (male)	110 (85.94)	108 (82.44)	218 (84.17)	0.441
Age (mean±SD)	61.62±7.95	61.11±6.76	61.36±7.37	0.579
Job				0.139
Employed/retired	98 (77.16)	105 (81.39)	203 (79.30)	
Housewife and/or Unemployed	29 (22.83)	24 (18.60)	53 (20.70)	
Income				0.007
Lower tertile	66 (52.38)	60 (47.62)	118 (46.09)	
medium and high	52 (40.00)	78 (60.00)	138 (53.91)	
A history of high blood pressure	45 (35.16)	40 (30.35)	85 (32.82)	0.428
History of High Cholesterol	60 (46.88)	42 (32.06)	102 (39.38)	0.015
History of fatty liver	10 (7.81)	10 (7.63)	20 (7.72)	0.957
History of pulmonary disease	10 (7.81)	11 (8.40)	21 (8.11)	0.863
History of cancer	0 (0.0)	1 (0.76)	1 (0.39)	0.322
History of Gastroenteritis disease	19 (14.84)	18 (13.74)	37 (14.29)	0.800
Family history of MI	40 (32.52)	40 (33.33)	80 (32.92)	0.893
History of angiography	116 (90.63)	109 (83.21)	225 (86.87)	0.077
History of angioplasty	102 (79.69)	91 (69.47)	193 (74.52)	0.059
Smoking (ever)	84 (65.63)	85 (66.93)	169 (66.27)	0.826
Education status (diploma and above)	37 (28.91)	49 (37.40)	86 (33.20)	0.147

Results

Overall, 259 people participated in this study. The basic characteristics of the participants, at the time of diagnosis, are shown in Table 1. The mean age of participants was 61.36 ± 7.37 and 84.17% of them were male. Both groups had similarities in basic characteristics, however the income status (P = 0.007) was significantly higher in the intervention group, and the history of high cholesterol was significantly higher in the control group (P = 0.015).

The Re-hospitalization and return-to-work rates in 6 and 12 months as well as, participants' mortality rates for the 6, 12, and 60 months were shown in Table 2. The results showed that the overall 5-year mortality rate in the participants was 8.30% (95% CI: 5.33% - 12.68%, n = 19). The difference in the 5-year mortality rate between the two groups was reported at 4.44% (the intervention group was 6.09% (n = 6) and the control group was 10.53% (n = 9)), but the difference was not statistically significant (P = 0.225).

Also, the mortality rate of all participants in the 0-6 months was 2.61% (95% CI: 1.17% - 5.71%, n = 6). The mortality rate of participants during 6-12 months was 0.5% (95% CI: 0.06% - 3.21%, n = 1), and the mortality rate of participants during 1 year to 5 years period was 5.41% (95% CI: 3.08% - 9.31%, n = 12).

The results showed that the average percentage of re-hospitalization in the first period (0-6 months) in all participants was 11.11% (n = 22, in the intervention group = 11.71% vs. the control group = 10.53%, P = 0.778). In addition, the percentage of re-hospitalization during the 6-12 months period in all participants was 8.29% (in the intervention group = 5.13% vs. the control group = 12.0%, P = 0.067).

Also, the average percentage of return to work in the first period in all participants was 95.58% (intervention group = 99.08% vs. control group = 92.31% P = 0.032) and the difference between the two groups was statistically significant. However, at the one-year evaluation, the percentage of returning to work in all participants was 96.74% (n = 189 in the intervention group = 96.58% versus in the control group = 96.94% P = 0.883).

Impact of intervention

The results of crude and adjusted logistic regression are shown in Table 3. Our results showed the crude odds ratio of death after 5-year follow-up increased by 9% for one year increase in age (OR = 1.09, 95% CI: 1.01 – 1.17, P = 0.026); this odds ratio remained the same after adjusting for the setting of the care. Also, the crude odds of death in the intervention group were 45% less than in the control group (OR = 0.55, 95% CI: 0.21 – 1.45), this association was not statistically significant (P = 0.229). In addition, the adjusted odds ratio with the age of participants showed the odds of death for the intervention group was 47% less than the control group (OR = 0.53, 95% CI: 0.19 – 1.50, P = 0.232). Sufficient evidence was not found to show a statistically significant association between other variables with the mortality rate in the participants [Table 3].

Discussion

This study was conducted to evaluate the effect of home based CR compared to comprehensive CR in mortality, re-hospitalization, and returning to work in patients who

Table 2: The number and rate of re-hospitalization, failure to return to work, and mortality in the period of 6 months, 12 and 60 months

Variable	Groups	0-6 month *n* (%) (95% CI)	0-12 month *n* (%) (95% CI)	0-60 months *n* (%) (95% CI)
Re-admission	Control	12 (10.53) (6.02, 17.76)	12 (12.00) (6.87, 20.12)	-
	Home care	13 (11.71) (6.86, 19.27)	6 (5.13) (2.29, 11.07)	-
	Total	25 (11.11) (7.60, 15.97)	18 (8.29) (5.27, 12.82)	-
Not returning to work	Control	9 (7.69) (4.01, 14.25)	3 (3.06) (0.97, 9.23)	-
	Home care	1 (0.92) (0.12, 6.41)	4 (3.42) (1.27, 8.87)	-
	Total	10 (4.42) (2.38, 8.06)	7 (3.26) (1.55, 6.71)	-
Mortality rate	Control	4 (3.39) (1.26, 8.80)	4 (3.96) (1.47, 10.24)	12 (10.53) (6.02, 17.76)
	Home care	2 (1.79) (0.44, 7.00)	3 (2.52) (0.80, 7.64)	7 (6.09) (2.90, 12.34)
	Total	6 (2.61) (1.17%- 5.71)	7 (3.18) (1.51, 6.56)	19 (8.30) (5.34, 12.68)

Table 3: Predictors of mortality risk after five-year follow-up: results of logistic regression

Predictors	Crude OR			Adjusted OR		
	OR	95% of CI	*P*	OR	95% of CI	*P*
Setting of care						
Hospital care	1			1		
Home care	0.55	0.21-1.45	0.229	0.53	0.19-1.50	0.232
Age	1.09	1.01-1.17	0.026	1.09	1.01-1.18	0.027
Sex						
Female	1			1		
Male	0.65	0.21-2.09	0.468	0.46	0.09-2.26	0.339*
Job						
Employed/retired	1			1		
Housewife/Unemployed	1.91	0.74-4.92	0.177	1.31	0.41-4.21	0.651*
Income						
Low	1			1		
High	0.73	0.29-1.88	0.520	0.73	0.25-2.12	0.564*
Education						
Lower than diploma	1			1		
≥diploma	0.90	0.33-2.48	0.844	1.38	0.43-4.44	0.593*
Smoking history						
No	1			1		
Yes	1.57	0.54-4.53	0.404	1.30	0.41-4.12	0.657*
Angioplasty						
No	1			1		
Yes	1.94	0.75-5.03	0.171	2.04	0.74-5.61	0.168*
History of MI						
No	1			excluded due to a small sample size		
Yes	0.49	0.14-1.73	0.268			
Gastroenteritis history				excluded due to a small sample size		
No	1					
Yes	0.33	0.04-2.59	0.294			
History of pulmonary disease				excluded due to a small sample size		
No	1					
Yes	0.56	0.70-4.42	0.581			
Fatty liver history						
No	1			1		
Yes	0.59	0.74-4.70	0.620	0.53	0.17-1.69	0.284*
History of hypertension						
No	1			1		
Yes	1.19	0.45-3.16	0.724	1.24	0.42-3.71	0.694*

* excluded from the final adjusted analysis due to $P>0.05$

survived an MI. The results of this study showed a significant difference between the rate of return to work during the 0–6-month period after MI (intervention group = 99.08% vs. control group = 92.31% $P = 0.032$). However, the rate of return to work during the 6-12 months (intervention group group = 96.58% versus in the control group = 96.94% $P = 883$) was not statistically significant. In addition, the rehospitalization rate was higher in the intervention group during the 0-6 months (11.71% than the control group = 10.53%, $P = 0.778$) and 6-12 months (in the intervention group = 5.13% vs. the control group = 12.0%, $P = 0.067$). Also, the death rate for the intervention group during the period of 0-6 months was less than the control group (1.79% vs. 3.39%, $P = 0.448$), this repeated during 6 to 12 months follow-up (2.52% vs 3.96%, $P = 0.360$) and 12-60 (6.09% vs. 10.53%, $P = 0.225$). However, these fewer risks were not statistically significant, which may be due to sample size. In addition, adjusted logistic regression reported the odds of death in the home care group, 47% (OR = 0.53, 95% CI: 0.19 – 1.50, $P = 0.232$) less than the control group.

Assessing the difference between two groups is a complex and multivariable issue that may be affected by biases or confounders. This study controlled some biases such as selection bias, with randomization to distribute patients randomly across care groups. Confounding variables like age and comorbidities were adjusted in the analysis.

Blinding of data collecter and data analyst used to prevent information biases. Also, this study was designed at 80% power and data were collected from a referral hospital in heart health services. Hence, the reliability, and internal and external validity of this study are acceptable.

Previous studies have shown inconsistent results regarding the impact of home care on re-hospitalization rates. The study of Khera *et al*.[13] reported an increase in re-hospitalization and a systematic review study by Zwisler *et al*.[14] showed no difference in re-hospitalization readmission.[15] Patient characteristics, such as disease severity and general health, may influence the rate of return to work and contribute to the observed differences.[15,16] Patients with severe conditions usually need more rehabilitation periods to return to work.[17] In addition, the duration of care, follow-up by the health care system, and access to resources are some of the main factors of return to work.[18,19] On the other hand, some variables that were not evaluated in this study, such as follow-up and monitoring of jobs, job requirements, psychological support, geographical and environmental factors, employer support, and type of job, can affect the rate of return to work.[18,20,21] However, the design of this study and the random allocation of participants to two groups have controlled these factors to some extent. These factors also may affect the rehospitalization of patients in addition to the willingness of treated patients at home due to greater comfort may help reduce the likelihood of rehospitalization.[22,23]

Mortality rate is an important measure of patient outcomes and reflects the effectiveness of different care methods. In our study, randomization ensured comparable severity of disease between the 2 groups and allowed us to attribute differences in mortality to the care setting. Some previous studies have reported a reduction in mortality in-home care,[10,13] but a systematic review study and meta-analysis conducted on heart failure patients reported no difference in mortality in patients.[14] Also, previous studies suggest that less severe patients may choose home care to maintain their independence and comfort.[24-26] While more acute patients choose hospital treatment due to immediate access to specialized medical facilities and therapeutic-supportive care specialists in hospital care.[27-29] However, the hospital environment may have risks such as hospital-acquired infections that can affect mortality.[29,30] This risk of infection also may contribute to the higher rate of hospital readmissions among those receiving hospital care.[31,32]

Generally, patients and healthcare teams must carefully evaluate the advantages and disadvantages such as the patient's health status, cultural-social considerations, risk of hospital infections, the patient's satisfaction, etc., with both methods, and make informed decision-making based on overall well-being and safety.[26,33,34]

Strengths and limitations

This study was conducted as a randomized clinical trial. Among the strengths of this study is the high internal and external validity due to the variety of patients, random allocation, implementation of a systematic protocol, and the implementation of the study by experienced personnel at the Cardiac Rehabilitation Research Center of Cardiovascular Research Institute, Isfahan. However, one of the limitations of this study is its relatively small sample size. The power of the study was calculated at 80%, but some associations reported insignificant results while they had important clinical effects and a low sample size may affect this association. On the other hand, a 12% loss to follow-up, further reduced the study's power and potentially introduced attrition bias. However, the rate of loss to follow-up was the same in both groups and reduced the power of the study.

Conclusions

The results of this study showed the odds ratio of death after 5-year follow-up increased by 9% for a year increase in age. Although the risk of death in home based CR, was 47% less than in the control group, this association was not statistically significant and no significant differences were found in re-admission rates or return to work within 12 months. Based on our findings, while home based CR may offer certain benefits, it does not significantly impact key clinical outcomes compared to comprehensive CR. Hence, the choice between home based and comprehensive CR should be personalized and made through joint decision-making. Future research is suggested to be conducted on larger, more diverse populations, long-term outcomes beyond 5 years, and quality-of-life measures to covermo the full implications of home based CR.

Ethical consideration

The main project was approved by the ethics committee of National Institute for Medical Research Development (IR.NIMAD.REC.1394.019) and Iranian Registry of Clinical Trials (IRCT2016022926820N1). A part of this project, approved by Isfahan University of Medical Sciences as a MSc dissertation and Ethical code was obtained from the Isfahan University of Medical Sciences' Ethics Committee (IR.MUI.RESEARCH.REC.1401.065). The participants were given information of the study's aims, methodology, and randomization at the outset. An informed consent form was completed by each participant. Every participant was free to leave the research at any time without incurring penalties or interfering with their regular medical care.

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Conflicts of interest

There are no conflicts of interest.

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