Community-based Cardiac Rehabilitation Improved Adherence to Medication, Quality of Life and Rehospitalization Among Stable Coronary Artery Patients: A Cohort Study

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\textbf{Keywords:}
Community-based cardiac rehabilitation; medical adherence; QoL.

\textbf{Abstract}

\textbf{Background:}\ Community-based cardiac rehabilitation interventions have been known as an important aspect of secondary prevention. However, no data are available regarding the benefit of this program in Indonesian coronary artery disease (CAD) patients treated with optimal medication.

\textbf{Objectives:}\ To assess the benefit of community-based cardiac rehabilitation on patient adherence to the drugs, quality of life (QoL) and MACE, in stable CAD.

\textbf{Methods:}\ An observational prospective cohort study recruited the Malang community of cardiovascular care (MC3) members as an intervention group and Aisyah Islamic hospital patients in Malang, Indonesia, as a control, for a year follow up. Member of MC3 has regular aerobic exercise, education regarding the disease, the importance of the drugs, and its side effect in addition to standard education given in outpatient clinic setting as the control group members. A validated MMS-8, QOL (SF-36), and SAQ questionnaire were used to assess adherence to the drugs, QoL, and MACE of participants.

\textbf{Results:}\ A total of 73 interventions and 73 control patients were enrolled for the study. Our findings showed that intervention patients were 2.04-fold associated with having a better physical function and 3.85-fold better compliance than control patients. The hospitalization rate also significantly lower in members of the intervention group (MC3). However, no significant difference observed among the two groups. Moreover, in the subgroup analysis, it shows that the intervention group who had participated for 2 years had the highest value of MMS-8 compared to the other groups with p < 0.005.

\textbf{Conclusion:}\ Our study reveals that community based cardiac rehabilitation intervention have better adherence to medication and quality of life than patients control, and also could reduce rehospitalization in stable CAD patients.

1. Introduction

Cardiovascular disease is a major cause of heart failure and premature deaths worldwide. It contributes substantially to the increase in health care costs.\textsuperscript{1} The previous study showed 48% of deaths in the world were caused by cardiovascular disease. A cohort study at the Harapan Kita National Heart Center and 5 hospitals in Indonesia suggested that the death rate due to heart disease in the hospital was around 6-12% and the re-hospitalization rate was 29%.\textsuperscript{2} Hidayat et al. reported that the total cost of INA-CBG claim for in-patient services for 18 months was Rp 42.4 trillion.\textsuperscript{3}

Up to now, the therapy for stable coronary artery disease was medical treatment in accordance with the recommendation, because it was proven to improve symptoms and prognosis unless progression of worsening occurred should be sent for revascularization. Revascularization either with percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) is more effective in treating angina, reducing of anti-angina drugs need, improving exercise capacity, and quality of life, compared to medical treatment strategies alone.\textsuperscript{4} After revascularization procedures, the coronary artery disease (CAD) patients recommended to perform in hospital base followed by community based cardiac rehabilitation.
Community based cardiac rehabilitation intervention consists of education regarding the natural history of the disease and its complication, the importance of drug adherence, and their side effects. The modality therapy of lifestyle changes, modification of risk factors, weight loss, self-management skills, and psychosocial factors were also part of cardiac rehabilitation modules.1,5

Community-based cardiac rehabilitation interventions have been developed to improve the patient's adherence to the guideline recommendations, with more or less impact on the achievement of outcome improvement.4 Adherence to the recommended-treatment has a favorable effect on morbidity and mortality in the follow-up period.6 However, no research has been done in Indonesia measuring the role of community-based cardiac rehabilitation on the adherence of patients with stable coronary artery disease.

Our current study, therefore, aimed to evaluate the impact of community-based cardiac rehabilitation on the patient's adherence. Our results were supposed to provide the benefit of community-based cardiac rehabilitation in reducing morbidity and mortality rates as well.

2. Method

2.1. Study design

A prospective cohort study was conducted in RSI Aisyah Hospital and Malang community-based cardiac rehabilitation (MC3) during 1 year period to determine the clinical outcome differences in drug adherence and MACE (Major Adverse Cardiovascular Event) reduction in stable coronary artery disease.

2.2. Participants & eligibility criteria

Subjects were patients diagnosed with coronary artery disease with revascularization-based therapy and optimal medical therapy divided into 2 groups (73 patients as controls and 73 patients with community intervention). All patients also were encouraged to comply with drug and healthy lifestyles during out-patient visits. This study used purposive sampling, patients who had been selected as subjects had fulfilled the inclusion criteria. The inclusion criteria for the intervention group were (1) Patients are members of the Malang Cardiovascular Care Community (MC3) and routinely participate in the activities of the community-based cardiac rehabilitation (MC3), (2) Age more than 40 years old, (3) Diagnosed as stable coronary heart disease that has been treated with optimal medication for 1 year, (4) willing to take medication after undergoing primary / elective PCI procedures, or CABG. For the control group, the inclusion criteria were the same except they did not a member of MC3 and did not participate in cardiac rehabilitation intervention programs. Patients with the following co-morbid conditions: structural heart disease, life expectancy less than 1 year, had a physical disability that limits daily activity and had psychological disorders were excluded from the study.

2.3. Ethical approval

The study protocols were conducted in accordance with the Declaration of Helsinki and were approved by the Institutional Review Board, Faculty of Medicine, Universitas Brawijaya, Malang, Indonesia (No: 400/122/K.3/302/2019). The aims, risks, and benefits of the study were explained to each participant, and they were asked to sign a consent form prior to enrolment in the study. Participants were also informed that they could quit at any time during the interview session. After informed consent was obtained, the interviewers conducted the structured interviews. Participation in this study was voluntary and no incentive was given.

2.4. Data Collection

A total of thirteen physicians was recruited as interviewers. The questioners of drug adherence using validated MMS-8, quality of life assessment using SF-36, and SAQ were filled to the subjects either MC3 members or non-members at the early and the end of the study. A set of validated questionnaires (SF-36) adapted from previous studies was used. Information-related to demographic data was collected using structured interviews. While information-related to the clinical conditions of the patients was retrieved from medical records with the patient's consent.

2.5. Measure

The demographic data included age, gender, educational level, marital status, residence, and family history of cardiovascular death. The conversion of date of birth into actual age was used to measure the age. Educational level was indicated by the highest level of formal education completed. The marital status of the patient as stated on identity card is divided into married and unmarried (death, divorced, never married). Monthly income, the average of the money earned each month, was measured by asking the participants to choose the closest amount of money from a list. The data was completed with a patient medical history obtained from medical records regarding the history of diabetes mellitus, hypertension, heart failure, and stroke. Patient compliance can be defined according to MMS-8 Morisky values for all heart medications prescribed by cardiologists, with a value <6 being said to be poor adherence, and ≥6 is said to be good adherence. In addition, data regarding the history of treatment, intervention, and echocardiography were also obtained from the medical record added to the questionnaire data. Qol was assessed using the eight specific and the two Physical and Mental Components Summaries (PCS and MCS) of the SF-36 health questionnaire.

2.6. Statistical Analysis

The data were analyzed using SPSS 22 software to determine the relationship between groups with community-based cardiac rehabilitation interventions with control of adherence to medication, quality of life, and MACE. MACE included in this study were death, recurrent revascularization, and rehospitalization. In addition, a test was conducted to assess the average difference in the value of the MMS-8, SAQ, and SF-36. To find out the difference in mean values of MMS-8, SAQ, and SF-36 before and after the intervention, we used a difference in mean delta values between groups of patients before and after treatment. Subgroup analysis in this study used the one way ANOVA. The p-value is considered to be significant if p <0.05. The degree of trust used is 95% (α = 0.05). Kaplan Meier analysis was used in this study, to analyze survival analysis, aimed at estimating the probability of survival, recurrence, death, and other events up to a certain time period.

3. Results

3.1. Patients selections

A total of 163 patients was identified. Of those, 17 patients were excluded because there was no evidence of coronary heart disease. Finally, we included 146 patients in our study, consisting of 73 patients Intervention group and 73 patients control group. A flowchart describing the eligibility pathway in our study is provided in Figure 1.

3.2. Baseline characteristics

The majority of participants were men (74.3%), the average age of patients was 59.8 ± 7.64 years and the mean of BMI was 25.9 ± 3.41 kg / m2. More than one-third of the participants were university graduates (48.6%). Regarding marital status, (52.1%) were married and 45.8% of the sample were supported socially. The majority (88.5%) of patients had undergone PCI for one or several coronary artery disea-
Patients didn't have coronary heart disease

17 Patients didn't have coronary heart disease

17 patients were excluded

Pre-test
(Basic Data and MMS-8, SF-36, SAQ)

73 Patients were attending community-based cardiac rehabilitation 4x/week

12 months follow-up
(evaluation MMS-8, SF-36, SAQ and MACE)

Intervention Group
90 Patients were recorded during May 2018

Pre-test
(Basic Data and MMS-8, SF-36, SAQ)

73 Patients assigned to the control group receive the usual care given in RSI

12 months follow-up
(evaluation MMS-8, SF-36, SAQ and MACE)

Control Group
73 Patients

Figure 1. A Flowchart of patients selection in our study

3.3. Main findings

The results of univariate analysis showed that there was no significant difference between the intervention group (MC3) and the control group (RSIA) on the basic characteristic values (age, sex, marital status, education, social support, and weight), history of comorbidity (diabetes mellitus, hypertension, stroke, dyslipidemia, heart failure), and history of treatment. The results of the univariate analysis are illustrated in Table 1. Our overall analysis found that MMS-8 score was significantly higher in intervention patients than control ones (7.5 ± 2.4 compared to 5.2 ± 1.90, p = 0.000), suggesting that higher adherence to medication in intervention group. The intervention group had also significantly lower MACE than the control group (OR 0.78, 95% CI 0.62-0.68), as shown in table 3. There was a statistically significant difference in clinical outcomes for MACE which is being lower in patients with good adherence. However, there was no significant difference in the quality of life parameters between a group of patients with MMS-8 ≥6 compare to MMS-8 <6, except for physical function and angina stability (p = 0.02 and 0.0, respectively), suggesting better angina stability and physical function in patients with better adherence to the drugs, as shown table 4. Rehospitalization was significantly lower in patients with MMS-8 ≥6 than those of MMS-8< 6 with a p-value = 0.03. Subgroup analysis suggested that the most common cause of rehospitalization was heart failure. No significant difference between groups was shown in the proportion of angina and myocardial infarction, see table 4. There was also a significant difference in free of heart failure during the 12-month follow-up between patients with good adherence (MMS-8 ≥6) and patients with poor adherence (MMS-8 <6), as described by the Kaplan Meier curve in figure 2. The prediction of acute myocardial infarction occurred in patients with good compliance and poor compliance was illustrated in figure 3. No obvious differences observed between the two groups.

During 12 months of follow-up, the patient with poor compliance showed 3 patients died due to cardiac causes (2 patients had heart failure, and 1 patient had myocardial infarction). However, no significant difference statistically observed in the mortality between the patients with good compliance and patient with poor compliance with p = 0.09. The Kaplan Meier curve showed the absence of mortality in intervention patients and control ones (figure 4).

3.5. Reduction of rehospitalization in intervention group

The proportion of rehospitalization of patients in intervention group was significantly lower than the control with a p-value = 0.012. From the subgroup analysis, it was found that the most common cause of rehospitalization was heart failure (see table 5). There were also significant differences in free of heart failure during the 12-month follow-up between patients with intervention and controls as described by the Kaplan Meier curve in Figure 5. Whereas the proportion of angina and myocardial infarction seemed to be no significant difference between groups. The prediction of the occurrence of acute myocardial
infarction in the intervention group and controls as illustrated in Figure 6. Unfortunately, no mortality difference observed between 2 groups during 12 months of follow-up. The Kaplan Meier curve predicts survival in intervention and control patients illustrated in Figure 7.

To provide comprehensive findings, we also performed a sub-group analysis. The subjects of this study were differentiated in accordance with their age, sex, education, and marital status. In the subgroup analysis, it showed that the intervention group who had participated for 2 years had the highest value of MMS-8 compared to the other groups with \( p = 0.000 \). The subgroup analysis result is shown in Table 6.

Table 1. Baseline characteristics of patients included in this study

| Characteristics                      | Intervention group (n = 73) | Control group (n = 73) | \( p \)  |
|--------------------------------------|----------------------------|-----------------------|---------|
| Age (year)                           | 60.34±7.02                 | 59.35±8.1             | 0.426   |
| Male                                 | 82%                        | 65.7%                 | 0.052   |
| BMI                                  | 24.13±3.08                 | 25.3±3.54             | 0.034   |
| Waist circumference                  | 74.5±8.83                  | 76.8±4.06             | 0.088   |
| Body height                          | 161.17±5.8                 | 162.1±6.85            | 0.845   |
| Mid upper arm Circumference          | 28.65±3.63                 | 31.17±3.6             | 0.52    |
| Education degree, undergradate       | 44%                        | 56%                   | 0.49    |
| Married                              | 47.9%                      | 52.1%                 | 0.96    |
| Comorbidity                          |                            |                       |         |
| History of stroke                    | 9.0%                       | 8.6%                  | 0.762   |
| History of Hypertension              | 46.2%                      | 50.0%                 | 0.964   |
| History of DM                        | 14.1%                      | 11.4%                 | 0.667   |
| History of dyslipidemia              | 51.3%                      | 54.3%                 | 0.841   |
| History of HF                        | 5.7%                       | 14.1%                 | 0.157   |
| History of medication                |                            |                       |         |
| ACE inhibitor                        | 45.9%                      | 78.8%                 | 0.04    |
| ARB                                  | 51.1%                      | 20.7%                 | 0.01    |
| Bisoprolol                           | 64.4%                      | 60.3%                 | 0.25    |
| MRA                                  | 54.5%                      | 45.5%                 | 0.641   |
| ASA                                  | 70.5%                      | 74.4%                 | 0.56    |
| Clopidogrel                          | 84.6%                      | 78%                   | 0.43    |
| Ticagrelor                           | 1.7%                       | 11.5%                 | 0.063   |
| Statin                               | 74.4%                      | 72.2%                 | 0.48    |
| History of intervention              |                            |                       |         |
| OMT                                  | 8.5%                       | 9.1%                  |         |
| PCI                                  | 90.1%                      | 87%                   |         |
| CABG                                 | 1.4%                       | 3.9%                  |         |

Note, data were presented in mean ± SD or n(%); DM, diabetes mellitus; HF, heart failure; ACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker; MRA, mineralocorticoid; OMT, optimal medicamentosa treatment; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft.
Table 2. Difference between MMS-8 and MACE in the intervention and control groups

| Parameter | Intervention group (n = 73) | Control group (n = 73) | p |
|-----------|----------------------------|------------------------|---|
| MMS-8 | 7.5 | 5.2 | 0.000 |
| MACE | 0 | 3 | 0.000 |

Note, data were presented in mean ± SD or n(%); MACE, major adverse cardiovascular event; MMS-8, Morisky Medication Adherence Scale.

Table 3. MMS-8 and MACE after 12 months evaluation

| Parameter | Δ Intervention group (n = 73) | Δ Control group (n = 73) | p |
|-----------|-----------------------------|-------------------------|---|
| MMS-8 | 1.57 | 0.2 | 0.000 |
| MACE | 2.9 | 20.5 | 0.000 |

Note, data were presented in mean ± SD or n(%); MACE, major adverse cardiovascular event; MMS-8, Morisky Medication Adherence Scale.

Table 4. MMS-8 to MACE and QoL

| Parameter | MMS-8 <6 | MMS-8 >6 | p |
|-----------|---------|---------|---|
| SF-36 | | | |
| Physical function | 80.96±16.24 | 88.95±13.07 | 0.000 |
| Limitation due to physical health | 71.92±34.63 | 82.14±25.6 | 0.000 |
| Limitation due to emotional problem | 72.99±34.86 | 77.02±30.69 | 0.000 |
| Energy Fatigue | 74.64±18.72 | 76.75±17.83 | 0.000 |
| Psychological health | 82.79±29.70 | 88.17±22.61 | 0.000 |
| Social function | 85.08±15.20 | 86.67±15.5 | 0.000 |
| Pain | 82.79±29.70 | 88.17±22.61 | 0.000 |
| General health perception | 72.28±19.27 | 75.98±14.47 | 0.000 |
| Vitality change | 73.39±21.38 | 80.47±17.28 | 0.000 |
| SAQ | | | |
| Role limitation due to physical health | 80.04±15.27 | 85.51±14.81 | 0.000 |
| Angina stability | 80.33±15.27 | 85.51±14.81 | 0.000 |
| Angina frequency | 78.24±18.85 | 84.12±18.71 | 0.000 |
| Therapeutic satisfaction | 78.58±18.85 | 86.43±14.81 | 0.000 |
| Quality of Life / Illness perception | 84.92±14.89 | 92.20±10.56 | 0.000 |
| MACE | 22.8 | 5.5 | 0.000 |

Note, data were presented in mean ± SD or n(%); SAQ, self-assessment questionnaire; MACE, major adverse cardiovascular event.

Table 5. Comparison of rehospitalization between MC3 and controls

| Variable | Groups | p-Value |
|----------|--------|---------|
| Rehospitalization | MC3 | 4.2% | 88.95±13.07 | 0.000 |
| Cause Rehospitalization | MI | 2.4% | 88.17±22.61 | 0.000 |
| HF | 4.2% | 86.67±15.5 | 0.000 |
| Angina | 2.4% | 88.17±22.61 | 0.000 |
| Mortality | 0% | 75.98±14.47 | 0.000 |

Note, data were presented in mean ± SD or n(%); AHF, acute heart failure; MI, myocardial infarction.

Table 6. Subgroup analysis

| Parameter | MMS-8 <6 | MMS-8 >6 | p |
|-----------|---------|---------|---|
| Educational level | >S1 | 40% | 37.8% | 0.85 |
| Age | > =65 | 15.8% | 31.9% | 0.034 |
| Sex | Male | 78.9% | 71.4% | 0.40 |
| Marital status | Married | 91.2% | 96.7% | 0.28 |

Note, data were presented in mean ± SD or n(%).

Figure 2. Kaplan meier AHF with MMS <6. ≥ 6
4. Discussion

This study has shown that community-based cardiac rehabilitation resulted in a reduction of rehospitalization, after analyzing the subgroup it found that the most common cause of rehospitalization was acute heart failure. These facts related to the higher adherence in the intervention group as shown by the MMS-8 score which is higher in MC3 as the intervention group. There was a significant relationship in increasing treatment adherence in patients with intervention and control with a significance level ($p = 0.000$). This was in accordance with previous studies conducted by Lixuan Zhang et al., Dabek et al., and ETICA trial which suggested the same results with this research. Data from the bivariate analysis showed that the intervention group had a lower MACE incidence than the control group. In accordance with research conducted by Kashish Goel et al. which states that the community-based cardiac rehabilitation group with a subset of patients after revascularization with PCI showed lower MACE numbers compared to controls. The previous study conducted by Sarah Canyon et al. has also suggested the same results during 12 months of follow up. However, no significant difference in total mortality observed among 2 groups, even if no death in the intervention group while in the control group 3 patients had 2 deaths due to acute heart failure, 1 patient had re-infarction during 12 months of follow up. The lacking of significance statistically in this study because of the small sample size and duration of follow up since a positive trend was observed. The bigger sample size and longer follow warrant to address this issue. The previous systematic review by O’Conor and Olridge has been suggested a reduction in
mortality rates from all causes both cardiac and non-cardiac in the intervention group. Therefore, Community-based cardiovascular prevention programs are a strategy widely recommended in public health. As our knowledge so far, no study has reported the impact of community-based interventions on compliance and quality of life.

In the subgroup analysis, it showed that the patients who have participated for 4 years had a significant highest score of MMS-8 compared to the other groups. While sex, age, educational level, marital status were not related to the MMS-8 score. These results suggested that longer duration of intervention resulted in higher adherence as measured by the MMS-8 score. On the contrary, a previous study revealed that the age group of 35-56 years old had the highest level of adherence and the age group of 56-64 years old had the lowest level of adherence. Conflicting results were revealed by several studies regarding the relationship between sex and adherence. The latest study showed that sex was not significantly related to non-compliance of treatment. Previous Eighteen randomized controlled trials demonstrated a low to moderate quality evidence on the improvements of medication adherence with educational interventions. Through education, health literacy is improved, thus improving medication adherence. The purpose of educational interventions is to empower patients with the knowledge and self-efficacy to make decisions and take responsibility for their medications. In addition, enhancing an individual’s understanding and confidence in their ability to manage their own conditions and improve their health literacy, which in turn has been found to be directly proportionate to more optimal disease management, greater involvement in self-care, and better clinical outcomes. Intervention components included some combination of heart health care management and/or education, counseling, exercise, or tele-health care. Usual care-control components typically were standard medical care that may have included a physician and/or specialist nursing care and heart education.

Research conducted by Dalal and Evans reported that after myocardial infarction patients who were given the choice turned out to prefer home/community-based cardiac rehabilitation rather than hospital-based, and of those who chose it as much as 87% completed their program. Community-based program offers the opportunity and early evaluations have reported improvements in exercise levels and reductions in angina similar to those reported by hospital-based programs. Group sessions allow patients to listen to questions that are asked by others.

The multifarious educational interventions augment the health literacy of individuals and find to moderately improve medication adherence by increasing their knowledge of their conditions, communications, and management. Early programs consisted of exercise training, whereas now a comprehensive approach is recommended, including assessment of risk factors, psychological and educational interventions, risk factor correction, stress management, and relaxation training, and delivered by a multidisciplinary group according to national standards. There was also limited data on the effects of health promotion programs and quality of life. A comparison of research results was difficult because of differences in the follow-up setting of each difference study in different time periods. The variety of methods, interventions, and study population also affected the different outcomes. However, there were several related studies that put our results in the same perspective. Improvements in components of quality of life have been reported after a cardiovascular lifestyle modification program for one year. However, only a study that did not report the beneficial effects of lifestyle programs on quality of life reported by Cupples & McKnight, which investigated the effects of a 2-year, five-year follow-up health promotion program. However, these studies focused on patients with high cardiovascular risk and based on interventions that were individually adjusted. Although many studies have attempted to improve compliance levels in activities in secondary prevention coronary artery disease, firstly, many of these are focused exclusively on the moment of hospital discharge, and secondly, the intervention takes place only on the physician. Thus, as a new element, our study prolongs the time of the intervention beyond hospital discharge, and moreover includes the patient as a participant in the achievement of objectives. The strengths of this research include (1) broad community support from doctors, community leaders, volunteers and hospitals involved; (2) The design of the study using cohort method so that it can assess changes in quality of life parameters after being intervened (3) stability of the population during the observation period as evidenced by the absence of patients dropping out during the intervention period. (4) MMS-8, SF-36, and SAQ questionnaires were questionnaires that have been tested for reliability and validity to improve quality of life. The community cardiac rehabilitation intervention was found to be related to increasing compliance and quality of life. These results suggest that this type of intervention can result in an improvement in the quality of care in this type of patients.

The limitation of this study was that this study was conducted on samples with different basic characteristics, especially when joining community-based cardiac intervention activities, to minimize this, the researcher uses subgroup analysis. The small sample size and a short follow-up period, thereby reducing the accuracy of clinical outcome data, especially mortality. It has been known that the presence of chronic diseases can have a negative impact on the quality of life. Therefore, the results of this study are adjusted for the presence or absence of a number of diseases such as stroke, type 2 diabetes mellitus, and heart failure. Unfortunately, no information is available about other chronic diseases (eg. Pulmonary disease (COPD), depression, and inflammatory bowel disease).

5. Conclusion

Our study revealed that the community base cardiac rehabilitation has been proven to have a better adherence resulting in a reduction of MACE, except mortality rate, and improvement of QoL.

6. Declarations

6.1. Ethics Approval and Consent to participate

This study was approved by local Institutional Review Board, and all participants have provided written informed consent prior to involve in the study.

6.2. Consent for publication

Not applicable.

6.3. Availability of data and materials

Data used in our study were presented in the main text.

6.4. Competing interests

Not applicable.

6.5. Funding source

Not applicable.

6.6. Authors contributions

Idea/concept: MDHK. Design: MDHK. Control/supervision: MSR. Data collection/processing: TA. Extraction/Analysis/interpretation: MDHK, TA, SW. Literature review: MSR. Writing the article: MDHK. Critical review: MSR, CTT, SW. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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