



Original Article:

The Long-Term Clinical Outcomes in Patients after Myocardial Infarction in Primary Care

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Abstract: The aim of this study was to investigate the effect of continuous multifaceted patient-centered interventions at primary care level in patients with myocardial infarction (MI) after discharge on achieving clinical practice guideline goals and reducing the rate of hospital readmissions for cardiovascular diseases. **Methods:** This prospective randomized clinical study was conducted enrolled patients with MI from January 2, 2017 to December 31, 2019. Patients received medication reconciliation and education from a family physician before hospital discharge. The intervention group (IG) received continuous consultations from the family physician after discharge, whereas the control group (CG) did not. Primary outcomes included achieving blood pressure < 140/90 mmHg, low-density lipoprotein-cholesterol (LDL-C) < 70 mg/dL, and hemoglobin A1c (HbA1c) < 7% targets. The secondary outcome was major adverse cardiac events (MACEs), defined as re-hospitalization due to MI, unstable angina and stroke. **Results:** Two hundred and nineteen patients completed the study protocol (110 in the IG and 109 in the CG). The rate of achieving blood pressure goal was similar between the two groups. More patients in the IG achieved LDL-C and HbA1c goals than those in the CG at 1 year and 2 years post discharge. However, there was no significant difference in the cumulative incidence of MACEs between the two groups. Diabetes was the only independent predictor of rehospitalization due to a MACE. **Conclusions:** Family physicians interventions led to a higher rate of optimal controlled modifiable risk factors but did not significantly reduce the MACE rate in the patients with MI.

Key Words: Myocardial infarction, Primary care, Family physician, Education.

Introduction:

Based on reliable data, the guidelines recommend comprehensive post-discharge myocardial infarction (MI) care that covers managing biomedical and lifestyle risk

factors, pharmacotherapy, assessing psychological factors, and helping to initiate and maintain behavioral changes [1, 2]. It is known that the interventions recommended in the guidelines reduce the risk of subsequent heart events in patients [3, 4]. However, as the duration of hospitalization for MI is reduced, most of the responsibility for treatment after discharge remains with the family physician.

It has been proven that the provision of primary care management to patients who have had MI improves the quality of life of patients and reduces the risk of secondary heart attack and the cost of re-hospitalization in the healthcare system. A person-centered approach attracts increased attention, probably because it attracts the patient as an active partner with capacities and ability to carry out actions and achieve goals [5]. Person-oriented care differs from traditional heart rehabilitation programs, which are focused exclusively on the disease and are carried out by health professionals [5, 6]. This approach has shown its effectiveness in terms of increasing self-efficacy after MI [1, 3, 6].

Understanding management in primary care and identifying gaps is important for improving the quality of care for a common, serious cardiovascular disease where unnecessary rehospitalizations can be avoided [7]. Given the high incidence of cardiovascular disease, relatively few studies have been identified regarding management in primary care after acute coronary syndrome. This is surprising given the importance of patient support at present, especially with respect to evidence-based medication and a healthy lifestyle to reduce the likelihood of a recurrence [7, 8].

Therefore, the aim of this study was to investigate the effect of continuous multifaceted patient-centered interventions at primary care level in patients with MI after discharge on achieving clinical practice guideline goals and reducing the rate of hospital readmissions for cardiovascular diseases.

Methods

Study design and setting

This prospective randomized clinical study was conducted in the centers of primary and secondary medical care in Kharkiv (clinical bases of the Kharkov Medical Academy of Postgraduate Education) from January 02, 2017 to December 31, 2019. We enrolled all patients admitted to our hospital with MI as the principle diagnosis from January 2, 2017 to December 31, 2017. The eligible patients were stratified by age (≥ 65 years and < 65 years) and sex, and were then randomized at a 1:1 ratio into the intervention group (IG) or the control group (CG). MI was defined as having elevated biomarkers for myocardial necrosis and clinical evidence including prolonged signs/symptoms of ischemia (> 30 minutes) or electrocardiographic ST-segment changes during the initial 24 hours of admission. The exclusion criteria were patients: (1) admitted for a primary non-cardiac diagnosis who developed MI as a secondary condition (such as perioperative MI); (2) discharged to a nursing home for long-term health care; (3) with irreversible, non-cardiac medical conditions (such as malignancy) which affected the 12-month survival rate or participation in the study; (4) who did not have access to a telephone for communication purposes.

The study was conducted in accordance with international standards of bioethics (Council of the European Convention on Human Rights and Biomedicine) and the recommendations of the Committee on Bioethics of the Ministry of Health of Ukraine. All patients signed an informed consent to participate in the study. This study was approved by the Ethics Commission of the Kharkov Medical Academy of Postgraduate Education of the Ministry of Health of Ukraine (Kharkiv, UA).

Study protocol and procedures

Once a patient had been identified, the cardiac unit nurse notified the family physician, and a schedule to complete consultations with the family physician was established within 3 days. The family physician then met with the patient for an initial interview consisting of general counseling with regards to cardiovascular diseases, education (monitoring their disease, reinforcing compliance to medications, therapeutic lifestyle changes, and how to take the medications), medication reconciliation and evaluation. Each interview lasted for approximately 1 hour, and the family physician recorded the details of the interview with each patient. The family physician was an experienced family physician with over 10 years of experience in providing consultations at the study hospital.

All patients were given an illustrated booklet before being discharged containing general information on the process and risk factors for cardiovascular diseases and emphasizing the importance of achieving recommended targets for BP, LDL-C, and HbA1c. The booklet also contained information about pharmacologic management as outlined in current practice guidelines.

The patients in the IG received detailed follow-up by the family physician every 3 months by telephone or in face-to-face visits and comprehensive chart reviews. The follow-up rate was 100% in the IG (110 patients). The regular contact and chart reviews were intended to provide adequate opportunities for the patients to ask questions, assess the patients' medication knowledge, discuss laboratory results, reinforce the importance of compliance with the medication regimen and achieving clinical targets, assess accuracy of the medications, appropriately monitor medication therapy and evidence-based chronic disease state management. Interventional feed-back was provided to the patient's physician and recommendations were made for any identified drug therapy problems. The patients assigned to the CG received no further contact with the study family physician.

All data collection was based on a review of the patients' medical records and interviews.

The goals for BP, LDL-C, and HbA1c were: BP $< 140/90$ mmHg (for patients with DM or chronic kidney disease $< 130/80$ mmHg); LDL-C < 70 mg/dL; and HbA1c $< 7\%$. If any of these risk factors were uncontrolled, the family physician alerted the patient by telephone, and their physician was notified by telephone for the patients in the IG.

Sample size and outcome measures

The study included consecutive patients with MI at a single facility between January 2017 and December 2017. The estimated sample size of 110 study patients in each group was based on an effective size with $\alpha = 0.05$, a power of 80%, anticipation of a 14.0% major adverse cardiovascular event (MACE) rate in the CG and 4.0% in the IG for the primary objective of this study. A 10% dropout rate was considered in both groups. Therefore, we screened 122 patients in each group. The primary end-points were differences in modifiable cardiovascular disease risk factors [systolic and diastolic BP, total cholesterol (TC), LDL, high density lipoprotein (HDL), tri- glycerides (TG), and HbA1c in those with DM] before (initial) and after (final) the study in both groups. The secondary end-point was MACEs including re-hospitalization for stroke, MI and unstable angina via the emergency department after hospital discharge. Stroke was defined as sudden onset of the loss of global or focal cerebral function persisting for more than 24 h. Unstable angina was defined as clinical evidence including prolonged signs/symptoms of ischemia (< 30 minutes) or without changes in electrocardiographic ST-segment and elevated biomarkers for myocardial necrosis. MI was defined as elevated biomarkers for myocardial necrosis and clinical evidence including prolonged signs/ symptoms of ischemia (> 30 minutes) or changes in electrocardiographic ST-segment.

Statistical analysis

We used a per-protocol approach for all analyses. Data were presented as the mean and standard deviation for normally distributed continuous variables, and proportions for categorical variables. Baseline characteristics and study results were compared using the chi-square test for categorical data, and the independent *t*-test, paired *t* test and analysis of cluster structure variability (ANOCVA) were used to compare continuous data between the two groups. The Kaplan-Meier method was used to determine the cumulative incidence of MACEs in both groups, and differences between groups were tested using the log-rank test. Cox regression analysis was used to determine the independent predictors for MACEs. A *p* value < 0.05 was considered to indicate statistical significance. All data processing and analyses were conducted using SPSS software, version 16.0 (SPSS Inc., Chicago, IL, USA).

Results

Patients

A total of 270 patients were screened, of whom 26 were excluded due to refusing to participate and six who were lost to follow-up. The remaining 244 patients were randomized into the IG ($n = 122$) and CG ($n = 122$). Of these patients, 9.8% (12/122) were excluded in the IG (all of whom were lost to follow-up), and 10.7% (13/122) were excluded in the CG (all of whom were also lost to follow-up). These 25 patients were not enrolled in our study for further analysis. All patients received follow-up at least every 3 months. The remaining 219 patients (110 in the IG and 109 in the CG) with a 100% follow-up rate were entered into the analysis. The last patient was enrolled on December 31, 2017, and follow-up was completed on December 31, 2019. All patients were followed for a minimum of 2 years. The family physician followed up the medical records and laboratory results to educate the patients on the importance of compliance with the medication regimen and achieving clinical targets. The family physician also

assessed the accuracy of medications and appropriate monitoring of medications in the patients in the IG. The follow-up rate with the family physician at each 3-month period was 100%.

Baseline comparisons

There were no significant differences in sex, age, education status, smoking history, renal function or body mass index between the two groups. With regards to modifiable risk factors, there were no significant differences in hypertension, dyslipidemia or DM between the two groups. More than 30% of the patients had one or two modifiable risk factors with a similar distribution between the two groups. Most of the patients did not have a coexisting disease, however in those who did, chronic kidney disease was the most common (IG 17.3% vs. CG 16.5%). There were no significant differences in the rates of medication use including antiplatelets (aspirin or clopidogrel), beta-blockers, ACEIs/ARBs and statins between the two groups at discharge (Table 1).

Table 1: Baseline demographic and clinical characteristics			
	Intervention group (n = 110)	Control group (n = 109)	p value
Male (%)	68 (61.8%)	67 (61.4%)	0.64
Age, years	61.2 ± 13.5	62.6 ± 13.3	0.43
≥ 65 years	38 (34.5%)	42 (38.5%)	0.45
BMI (kg/m ²)	21.8 ± 5.40	22.4 ± 7.30	0.36
Literacy rate (%)	99 (90%)	93 (85.3%)	0.25
Smoking (%)	45 (40.9%)	52 (47.7%)	0.26
Creatinine (mg/dL)	1.61 ± 2.15	1.49 ± 1.63	0.63
eGFR	58.25 ± 14.14	69.35 ± 14.22	0.38
Hypertension	88 (80%)	84 (77.1%)	0.85
Hyperlipidemia	86 (78.2%)	80 (73.4%)	0.66
Diabetes	42 (38.2%)	41 (37.6%)	0.71
CVA	8 (7.3%)	7 (6.4%)	0.74
CKD	19 (17.3%)	18 (16.5%)	0.87
Drug therapy			
Aspirin	97 (88.2%)	92 (84.4%)	0.55
Clopidogrel	83 (75.5%)	82 (75.2%)	0.76
Dual antiplatelet	83 (75.5%)	81 (74.3%)	0.72
β-blockers	88 (80%)	89 (81.7%)	0.64
ACEIs	58 (52.7%)	54 (49%)	0.58
ARBs	41 (37.3%)	40 (36.7%)	0.87
ACEIs or ARBs	99 (90%)	94 (86.2%)	0.93
Statins	95 (86.4%)	88 (80.7%)	0.39
ACEIs, angiotensin converting enzyme inhibitors; ARBs, angiotensin receptor blockers; BMI, body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; CVA, cerebrovascular accident; eGFR, estimated glomerular filtration rate; MRF, modifiable risk factor.			

Changes in blood pressure, lipid profile and hemoglobin A1c

Of the 172 patients with hypertension, there were no significant differences in systolic BP (SBP) or diastolic BP (DBP) at baseline, 1 year and 2 years after discharge. Of the 166 patients with hyperlipidemia, there were no significant differences in serum LDL-C, TC, HDL and TG between the two groups. However, the IG had a significantly lower serum LDL-C and higher HDL level than the CG at 1 year and 2 year after discharge. Among the 83 patients with DM, there were no significant differences in mean HbA1c between the two groups. However, the HbA1c level was lower in the IG than in the CG at 1 year and 2 years post discharge (Table 2).

Table 2: Changes in blood pressure, lipid profile and hemoglobin A1c levels within both groups before and after study

	Intervention group (n = 110)	Control group (n = 109)	p value
SBP at baseline (mmHg)	129.6 ± 18.7	129.3 ± 18.2	0.833
DBP at baseline (mmHg)	73.9 ± 9.8	72.9 ± 8.9	0.493
SBP at 1 year	132.9 ± 18.7	134.2 ± 19.3	0.485
DBP at 1 year	74.2 ± 10.4	74 ± 10.8	0.754
SBP at 2 years	134 ± 19.3	134.4 ± 17.8	0.296
DBP at 2 years	73.4 ± 9.7	74.2 ± 10.7	0.598
Lipid profile			
LDL-C at baseline (mg/dL)	113.3 ± 36.5	114.4 ± 35.6	0.518
LDL-C after 1 year	78.72 ± 25.4	89.9 ± 35.6	0.034*
LDL-C after 2 years	80.2 ± 24.6	85.2 ± 29.4	0.049*
HDL-C at baseline (mg/dL)	44.5 ± 12.7	47.6 ± 22.5	0.467
HDL-C after 1 year	50.5 ± 13.5	50.4 ± 12.4	0.005*
HDL-C after 2 years	51.7 ± 15.8	49.9 ± 12.4	0.005*
TC at baseline (mg/dL)	187.4 ± 44.4	179.3 ± 39.7	0.437
TC after 1 year	149.7 ± 32.4	160.7 ± 44.8	0.031*
TC after 2 years	152.5 ± 31.2	154.6, 33.2	0.440
HbA1c at baseline	6.61 ± 1.51	6.70 ± 1.49	0.636
HbA1c after 1 year	6.21 ± 0.89	6.56 ± 1.12	0.026*
HbA1c after 2 years	6.26 ± 0.91	6.76 ± 1.22	0.013*
* Analysis of cluster structure variability (ANOCVA). BP, blood pressure; DBP, diastolic blood pressure; HbA1c, hemoglobin A1c; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein-cholesterol; SBP, systolic blood pressure; TC, total cholesterol. 1 year: measurements at 1 year after discharge; 2 years: measurements at 2 years after discharge. # There were 84 patients and 88 patients with hypertension in control group and intervention group respectively. There were 41 patients and 42 patients with diabetes mellitus in control group and intervention group respectively. There were 80 patients and 86 patients with hyperlipidemia in control group and intervention group respectively.			

In addition, there were higher rates of prescriptions for medications for hypoglycemia and dyslipidemia in the IG. There were higher rates of multiple kinds of hypoglycemic drugs in the IG, however these changes were reversed in the CG. This finding indicated that the family physicians interventions were effective in achieving optimal blood sugar control by adjusting the kinds of drugs. Increases in the kinds of drugs used to achieve optimal blood pressure and lipid level were also found. The changes in medications indicated that the family physician interventions were beneficial in increasing the percentage of optimal modifiable risk factors control rate by notifying the cardiologist to adjust medications.

Rates of modifiable risk factor goals achieved after discharge

There were no significant differences in the proportion of patients who achieved BP goals at baseline, 1 year and 2 years post discharge between the two groups. However, the overall increase in patients achieving the BP goal was higher in the IG (18.6%; from 49.8% to 68.4%) than in the CG (12.2%; from 59.2% to 71.4%). In addition, the rate of achieving the lipid goal (LDL-C < 70 mg/dL) increased in both groups from baseline to 1 year and 2 years post discharge. Although the rate of achieving the lipid goal was lower in the IG at baseline, the rates at 1 year and 2 years post discharge were significantly higher in the IG than in the CG.

There were significant differences in the proportions of patients who achieved the HbA1c target (HbA1c < 7%) between the two groups at 1 year and 2 years post discharge

(all $p < 0.05$), with an increase of 29.5% (from 38.2% to 67.7%) in the IG and a decrease of 2.3% (from 34.5% to 32.2%) in the CG at 1-year post discharge. In addition, the rate of achieving the HbA1c goal was higher in the IG than in the CG at 2 years post discharge. Although there were no significant differences in the overall rates of controlled optimal modifiable risk factors between the two groups, the rates were higher in the IG than in the CG at 1 year and 2 years post discharge.

Table 3: Cumulative incidence of MACEs requiring emergency department visits			
	Intervention group (n = 110)	Control group (n = 109)	p value
Myocardial infarction	0.9% (1)	4.6% (5)	0.065
Stroke	0% (0)	1.8% (2)	0.527
Unstable angina	5.5% (6)	2.8% (3)	0.575
MACEs	6.4% (7)	9.2% (10)	0.372
MACEs - major adverse cardiac events.			

Cardiovascular events post discharge

Kaplan-Meier analysis showed no significant difference in the cumulative incidence of MACEs between the CG and the IG. The rate of re-admission for MI was slightly higher in the CG than in the IG. However, there were no significant differences in the rates of re-admission for stroke or unstable angina after hospital discharge between the two groups. There was also no significant difference in the rate of MACEs between the CG (9.2%) and IG (6.4%) (Table 3). Multivariate Cox regression analysis for MACEs showed that DM was the only an independent predictor of MACEs post discharge in the patients with MI (Table 4).

Table 4. Univariate and multivariate Cox regression analyses for MACEs requiring emergency department visits						
Variable	HR	95% CI	P value	HR	95% CI	P value
Age	1.027	0.974-1.082	0.582			
Male gender	0.451	0.198-1.045	0.071	0.526	0.455-3.532	0.684
BMI	0.989	0.773-1.236	0.871			
Obesity	1.563	0.667-3.670	0.328			
Creatinine	0.878	0.496-1.565	0.639			
Smoking	0.536	0.260-1.074	0.085	0.920	0.415-2.058	0.829
DM	2.715	1.377-5.363	0.011	4.254	1.041-4.592	0.045
HTN	2.214	0.859-5.783	0.116			
CVA history	6.179	1.297-29.75	0.012	2.698	0.799-9.186	0.125
CKD history	2.093	1.036-4.140	0.049	1.613	0.778-3.363	0.221
Baseline LDL	1.014	0.996-1.032	0.789			
Baseline HDL	0.996	0.964-1.048	0.998			
Baseline TC	1.012	0.996-1.028	0.899			
BMI - body mass index; BP- blood pressure; CI - confidence interval; CKD - chronic kidney disease; CVA - cerebrovascular accident; DM - diabetes mellitus; HR - hazard ratio; HDL-C - high-density lipoprotein cholesterol; HTN - hypertension; LDL-C - low-density lipoprotein- cholesterol; MACEs - major adverse cardiac events; TC - total cholesterol.						

Discussion

This study confirms that teaching self-management for patients after MI is vital. Patient' education was mainly delivered in primary care by FP.

The value of secondary prevention programmes during acute coronary syndrome recovery is well established [9], whereas incentives to accept and adhere to drug therapy [10] and to lifestyle recommendations have been shown to remain poor [11]. Low income and education level are associated with underuse of recommended drugs after MI [12]. An unhealthy diet pattern [13], due to several factors [14], is common and low physical activity is associated with socioeconomic status in patients with coronary heart disease [15]. After MI, lower return to work rates and increased probability for early retirement are associated with female sex, low education, basic occupation, co-morbidity and invasive procedures. Long-term sickness absence after coronary revascularisation is common and associated with socioeconomic status, female sex, comorbidity and sickness absence during the year before intervention [15]. The ethics on mutual respect and health care professionals' taking time to carefully listen to the patients' illness narrative is probably an important component in strengthening self-efficacy.

There were few interventional studies, so further research of ways to improve quality of care is clearly indicated. Future study should include efforts to improve the quality of care of special population groups must be customised to their particular needs [16]. It is clear that greater integration of hospital and GP management in the form of detailed discharge summaries and communication of management plans would allow for more effective patient care.

Unfortunately, motivating patients to fully participate and adhere to cardiac rehabilitation is a challenge. In most European countries more than 50% of eligible patients have been reluctant to participate. Additionally, non-attenders are more likely to have a low socioeconomic status [17] and although there have been improvements in global health in past years, inequalities persist that increase differences in cardiac health [18]. Consequently, despite the benefits of cardiac rehabilitation, it remains heavily underused [19]. To improve equity in uptake of cardiac rehabilitation more creative and dynamic ways of operating are needed.

However, this study shows that in a normal clinical situation, patients often do not understand what they are told, and, moreover, without this primary basis, the patient cannot justify the need for therapy. This aspect of the doctor-patient relationship was visited earlier, where it was claimed that doctors offered simple instructions several times, and yet the patient, mainly due to anxiety, does not receive such information. This gives the doctor a unique responsibility and the opportunity to act not only as a diagnostician, but also as a qualified teacher-teacher. In this regard, focus group participants give priority to the empathic qualities of the doctor, interests, hearing, and patient time.

This implies that there is a need for a new perspective on health care that goes beyond the biomedical side of medicine, and that doctors should interact more actively with patients and be able to study the patient's understanding of the world. To achieve this goal, it was proposed to use interpersonal communication skills among medical workers [20].

Compliant patients better understood their illness and possible treatment options. Committed patients better understood their disease and possible ways to treat this disease. They also had great confidence that the current leadership would keep their illness under control. Satisfaction and faith in treating physicians were found to be low among the less committed groups compared to the highly committed groups [21].

Concomitant disease is also one of the important factors responsible for non-compliance with the rules of therapy. It is known that depression is a risk factor for non compliance. In

this study, any specific questions about depression in the questionnaire were excluded because of the sensitivity of the topic and the concerns about the lack of patient response [22]. The recognition by the patient of the disease process and the recommended treatment, knowledge and faith in treatment, effective interaction between the patient and the doctor, and the routinization of drug therapy are crucial for not necessarily adhering to the treatment regimen in patients [23].

Limitations

There are several limitations to this study. First, the sample size was relatively small. In addition, the study was conducted at a single center. The study was an open-label design, and none of the participants were blinded to treatment assignment. These factors may have introduced bias and a double blind clinical trial with a larger sample size conducted at multiple centers warranted to validate our findings. Second, data on blood pressure were recorded from medical records at wards and outpatient clinics, and the effect of white coat hypertension cannot be excluded. Third, some confounders that could have affected BP, lipids and sugar control were not explored in detail. Fourth, MACEs were assessed by only two of the investigators in this open-label study. In addition, the use of unstable angina as a MACE was also prone to bias.

Conclusions

While there have been a growing number of efficacious pharmacological and non-pharmacological interventions for patients after MI, their effectiveness will be limited without self-management support to assist patients in adopting behaviours that contribute to improved health.

In this study, continuous multifaceted patient-centered family physician interventions led to improvements in the rates of achieving modifiable risk factors guideline goals, especially with regards to lipid and sugar control. Family physician interventions did not significantly reduce readmission rate after hospital discharge in the patients with MI.

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