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The Effects of Clinical Pharmacist Education on Lifestyle Modifications of Postmyocardial Infarction Patients in South India: A Prospective Interventional Study

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ABSTRACT

Background: Myocardial infarction (MI) is associated with significant short-term and long-term mortality and morbidity. Secondary prevention and treatment of post-MI patients through medication and lifestyle modification is becoming an important aspect of patient care regimens. Pharmacists have a crucial role in providing these disease-prevention interventions compared with other health care professionals.
Objectives: The primary objective included evaluation of clinical pharmacist interventions at discharge and post-MI discharge follow-up to improve the secondary lifestyle modifications and medication adherence among post-MI patients. The secondary objective included the prevention of hospital readmission rates for major adverse cardiovascular events and death among post-MI patients.
Methods: In this prospective interventional study comprising 160 screened patients, 154 patients were randomized according to eligibility criteria of whom 77 were enrolled in Group A (the intervention group: clinical care along with pharmacist education) and 77 in Group B (the control group: clinical care with usual counseling) (November 2017–April 2018). Two patients were lost to follow-up in both study groups. Group A patients received clinical care with pharmacist structured intervention at post-MI discharge and through telephone follow-ups, whereas Group B patients received clinical care with usual counseling at baseline. Patients in both groups were analyzed for secondary lifestyle modifications such as fasting blood sugar level; postprandial blood sugar level; blood pressure; and total cholesterol, LDL-C, HDL-C, VLDL-C, and triglyceride level; hospital readmission rates; and medication adherence at the baseline. At the end of 6 months patients in both study groups underwent follow-up. Medication adherence was analyzed using the Medication Adherence Rating Scale. Statistical analysis was carried out by using SPSS software version 17 (SPSS-IBM Inc, Armonk, NY).
Results: The mean (SD) age of the study population was 56.38 (11.68) years in Group A and 53.93 (13.26) years in Group B. Ther were more male patients than female patients in the study population. There was a statistically significant reduction in systolic and diastolic BP in Group A ($P > 0.0031$ and $P > 0.0069$, respectively) compared with Group B. Reduction in total cholesterol levels were observed in Group A compared with Group B ($P > 0.0001$) patients, but there were no significant reductions found in lipid profile values, including LDL-C ($P > 0.0669$), HDL-C ($P > 0.595$), triglyceride ($P > 0.119$), and VLDL-C ($P > 0.4215$) at follow-up. Group A patients were more adherent to the medications with lower hospital readmission rates compared with Group B.
Conclusions: Clinical pharmacist counseling improved the medication adherence and lifestyle modifications in post-MI patients with the reduction in blood glucose levels, blood pressure, and total cholesterol levels among the study population.

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Introduction

Myocardial infarction (MI) remains among the most dramatic presentations of coronary artery disease (CAD). MI is considered to be recurrent if features of MI occur after 28 days following an incident MI.[1] Two studies reported that the incidence rate of acute ST-segment elevation MI was found to be 60% and 37% of all acute coronary syndromes (ACSs) in India, respectively.[2] Data from the past 20 years shows that mortality rates after recurrent MI have subsequently declined.[3]

Complete occlusion of the artery often produces myocardial necrosis, the classical picture of a heart attack with severe chest pain, electrocardiographic changes of ST-segment elevation, and an elevated concentration of myocardial-specific proteins in the circulation that is described as ST-segment elevation MI. Intermittent or partial occlusion produces similar, but often less severe, clinical features although no or transient and undetected ST elevation occurs, which is described as a non-ST segment elevation MI. People who have experienced MI can be treated to reduce the further risk or other manifestations of vascular disease by means of secondary prevention. Recurring MI may put patients at risk of reduced quality of life, heart failure, and death. Post-MI therapy and secondary prevention of MI involve the use of medication therapy and lifestyle modifications. Patients with ischemic comorbidities surviving hospital discharge are at an increased risk of early readmission due to various factors such as age, medication nonadherence, metabolic disorders, other underlying comorbidities, early cessation of antiplatelet drugs, and inadequate planning of discharge.[4,5]

Despite improvement in pharmacological therapy and introduction of percutaneous coronary intervention, patients with ACSs are at a high risk for development of secondary cardiovascular events. Risk scores of thrombolysis in MI are a useful means to classify patients based on their subsequent risk and baseline characteristics.[6] A 2-year follow-up study found that electrocardiography showing infarct location, stent implantation with drug elution, and cholesterol levels were successful predictors of recurrent MI.[7]

After MI from either ST elevation or non-ST elevation, patients should be given indeterminate treatment with aspirin, a beta-blocker, and an angiotensin converting enzyme inhibitor as per American College of Cardiology/American Heart Association guidelines. Together with aspirin, most patients with non-ST elevation ACS must be given clopidogrel for up to 9 months. Warfarin medication can be given long-term for selected patients. A drug regimen for hyperlipidemia, principally statin drug therapy, will be required by a majority of patients with CAD.

Clinical pharmacists have direct involvement with physicians and other health care professionals to provide the medications that are prescribed to patients and contribute to the best possible health outcomes. Clinical pharmacists practice in the area of health care settings and have recurrent and regular interactions with medical practitioners and other health care professionals, all of which contribute to better coordination of care. Clinical pharmacists can play an active role in patient education regarding the usefulness of taking antiplatelet drugs and can bridge the gap between patients and physicians. Pharmacists can also promote rational drug use and encourage patients to manage their disease state with various lifestyle modifications.[5] They can also provide discharge medication counseling and provide postdischarge follow-up.[8] Pharmacists have in-depth knowledge and understanding of correct use of medicines and pharmacology. An observational study reported that cardiovascular drugs were the third-most erroneously prescribed drugs that demanded pharmacist intervention.[9] Therefore, the role of clinical pharmacists cannot be ignored. The present study was designed to assess the role of clinical pharmacists in providing advice on lifestyle modifications and improving medication adherence among post-MI patients in India.

Methodology

Study site, study design, and ethical considerations

A prospective randomized interventional study comprising 154 MI patients from cardiovascular and thoracic surgery and cardiology departments of a tertiary care hospital. This study was conducted according to the standards of the International Committee on Harmonization of Technical Requirements of Good Clinical Practice and the revised version of the Declaration of Helsinki. The institutional review board of Vels Institute of Advanced Sciences and Technology approved the study protocol (IEC/PHD2015/2016/01).

Study groups

The study included 2 groups: Group A (intervention group) received clinical care with pharmacist education. Clinical pharmacists delivered an intensive, structured intervention at discharge and tailored follow-up postdischarge at 6 months (an approximately 30-minute counseling session) and Group B (control group) received clinical care along with usual counseling delivered by a pharmacist at discharge. The usual care delivered by cardiologists was similar in both groups and there was no modification of level of care required.

Patient selection

Patients of both genders aged 18 years or older, admitted for management of MI requiring therapy such as percutaneous transluminal coronary angioplasty or coronary artery bypass graft were included for the study. Patients with heart transplant, heart valve surgery, heart failure, and other comorbidities were excluded.

Study procedure

A total 160 patients were assessed for eligibility of whom 6 patients excluded were because of their unwillingness and also because they did not meet inclusion criteria. The remaining 154 participants were divided into 2 groups using a computer-generated randomization chart. Group A was treated with clinical care with pharmacist education and Group B received clinical care and usual counseling. In the intervention arm (Group A), the clinical pharmacist provided verbal counseling to the study patients as well as addressed and documented the following points: generic names of medications, indications, doses/frequencies, adverse effects, medication adherence, reinforcement of physical activity, reinforcement of alcohol limits, and smoking cessation. Counseling sessions took place before a patient's discharge from the hospital, but not necessarily at the day of discharge at least for 30 minutes. The patient information leaflets (PILs) were explained and provided as supplementary materials to the patients during discharge. Group B received clinician care and basic counseling at discharge (including discussion of the discharge medications, follow-up details, and dietary instructions). Both groups were analyzed for secondary lifestyle modifications such as fasting blood sugar, postprandial blood sugar, blood pressure, lipid profile, and medication adherence. At the end of 6 months, follow-up was done for both groups. A flow chart of the entire study is in the Figure.

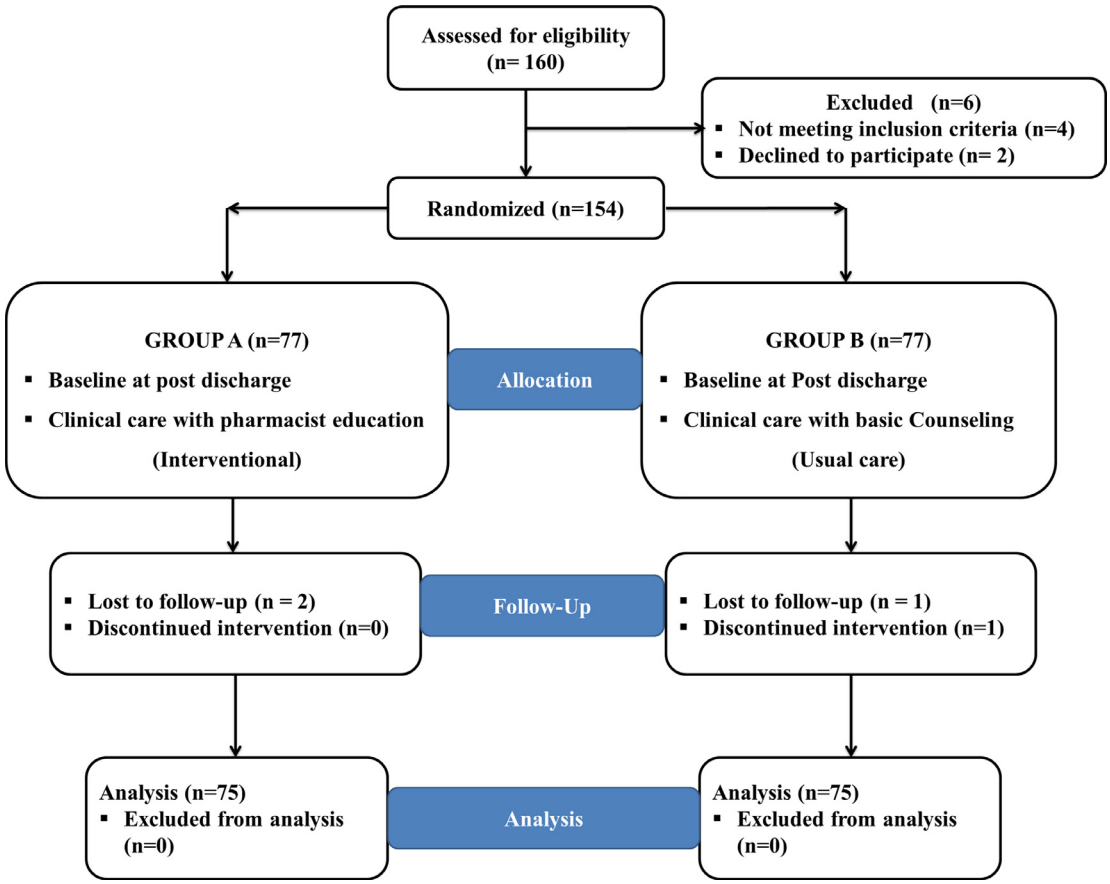

Figure. Flow chart showing the study design.

Collection of demographic information and blood pressure measurement

Demographic details of the included patients were collected and documented. Blood pressure was measured using a mercury-free LCD sphygmomanometer (BPDG 234 LCD Super Deluxe; Diamond, City, India); 2 readings were taken at 10-minute intervals after patients had been seated for at least 10 minutes with the help of qualified and trained nursing personnel. Two readings were averaged. Systolic blood pressure ≥140 mm Hg and diastolic blood pressure ≥90 mm Hg were considered high blood pressure.

Measurement of biochemical parameters

A venous blood sample (5 mL) was collected after overnight fasting. A 2 mL blood sample was transferred into sodium EDTA vacutainer then the plasma was separated by centrifugation for glucose estimation, remaining samples were transferred to plain tube and allowed to clot at room temperature for 45 minutes before centrifugation to separate the serum. Centrifugation was done through centrifuge-5430R (Eppendorf). The samples were then aliquoted into Eppendorf tubes and stored at −20°C until analysis. Plasma glucose and serum total cholesterol, triglyceride, HDL-C and LDL-C levels were determined through fully automated clinical chemistry analyzer (EM 360, Transasia) using Erba diagnostics kits (Erba Diagnostics Mannheim, GmbH).

Preparation of PILs

PILs were prepared in the local vernacular language Tamil and as well as in English based on the guidelines of the American Heart Association and UK National Institute for health and care excellence. The PIL was explained and provided as supplementary materials to post-MI patients during discharge. The content of PIL consists of the summary of MI symptoms, risk factors, management criteria, lifestyle modifications, diet counseling, and drug counseling.

Validation of PILs

The validation of PILs was carried out by the expert committee that consisted of specialist doctors (n = 3), postgraduate doctors (n = 2), nurses (n = 4), pharmacists (n = 3), and a cardiology department technician (n = 1). The primary model was submitted to the expert panel and all the necessary opinions and suggestions were the obtained from the committee.

Readability of the PILs

After the modifications, the PIL was prepared and readability was calculated by using Flesch reading ease (FRE) formula: FRE = 206.84 − 0.85W − 1.02S. Where W = number of syllables per 100 words and S = number of words in an average sentence. In the FRE scale, the scoring ranges between 0 and 100. Ideal PILs should have a readability score >80. It is generally considered that a PIL is difficult to read when FRE scale score <60.

Design and translations of PILs

The layout and design of the PIL was assessed by using Baker Able leaflet design criteria. The scores were calculated based on the length of the lines, space between the lines, letter type, font size, indenting, pictograms, box type text, use of colors, paper quality,

and so on. A score ≥25 is considered to be standard and good layout and design. The validated PILs were translated into Tamil and English languages by means of forward and backward translation.

Assessment of medication adherence

Medication compliance was assessed using the medication adherence rating scale (MARS) at the baseline and 6 months and through telephone interviews. The MARS contains 10 yes/no questionnaire items and the sum of items yields a final score ranking from 0 (poor adherence to treatment) to 10 (good adherence to treatment). Counseling regarding the lifestyle modifications and medications were reinforced at each of the telephone interviews, and the patients' understanding of prescribed medications were re-evaluated at the follow-up. Medication adherence was assessed only by patient responses to the questioning with no independent verification (eg, pharmacy records, pill counts, or electronic medication event monitoring systems).

Statistical analysis

Values are expressed as mean (SD) changes. The χ^2 test was used to analyze the differences in categorical variables such as demographic parameters. Both paired and unpaired *t* tests were used for analyzing laboratory values and medication adherence. Statistical analysis was carried out using SPSS version 17 software (SPSS-IBM, Inc, Armonk, NY).

Results

Patient demographic characteristics

In this prospective interventional study comprising 150 patients screened according to eligibility criteria, 75 patients were enrolled in Group A (clinical care with pharmacist education) and 75 patients were enrolled in Group B (clinical care with usual counseling). The pharmacist interventions such as patient education on drug therapy and secondary lifestyle modifications (eg, blood pressure control, blood glucose control, body mass index, diet, and alcohol and smoking cessation) were presented to patients at discharge through telephone interviews and during follow-up. Assessment of blood pressure, glucose levels, and lipid profile were done at baseline and 6 months. The mean (SD) age of the study population was 56.38 (11.68) years in Group A and 53.93 (13.26) years in Group B. Male patients were more affected with MI when compared with female patients. Age distribution; gender distribution; and distribution based on patient history, diagnosis, social history, family history of MI, and interventions are shown in Table 1.

PIL

The mean readability score of the final version of the PIL was found to be 88 on the FRE scale. This FRE score ensured that patients could read the PILs with ease. The mean Baker Able leaflet design criteria score of the PIL was 30, which ensured that patients could read and understand the PILs easily.

Lifestyle modifications and laboratory assessments

The clinical study parameters of the study population were measured and depicted in Table 2. Reduction in blood sugar (fasting and postprandial), blood pressure, and total cholesterol levels were observed in the pharmacist-counseled group compared with the usual care group. There were no significant reductions observed in LDL-C, HDL-C, VLDL-C, or triglyceride levels. Table 3 showed that there were 2 readmissions in Group A and 5 in Group B during the follow-up period. Reported adherence with medications measured using MARS improved in the pharmacist-counseled group compared with the usual care group (0.0001) as depicted in Table 4. Claimed adherence to medications improved in the pharmacist-counseled group due to patient education provided by the pharmacist that included drug therapy and secondary lifestyle modifications (ie, blood pressure and blood glucose control, body mass index, diet, and alcohol and smoking cessation). The mean (SD) MARS score for Group A was 9.48 (0.16) compared with Group B, which was 7.50 (0.17) with a significance of $P > 0.0001$. It was observed that the percentage of alcohol users and smokers was less in the pharmacist-counseled group compared with the usual care group (Table 5).

Table 1
Social and demographic details of the study population.

Clinical parameter	Group A (n = 75)	Group B (n = 75)	*P* value
Age* (y)	56.38 (11.68)	53.93 (13.26)	0.232
Male	57 (76)	65 (86.67)	0.094
Female	18 (24)	10 (13.33)	
Smoker	10 (13.33)	18 (24)	
Alcoholic	09 (12)	09 (12)	0.163
Tobacco chewer	04 (5.33)	01 (1.33)	
HTN	15 (20)	12 (16)	
DM	17 (22.67)	14 (18.67)	0.086
HTN/DM	13 (17.33)	18 (24)	
CAD/ACS	8 (10.67)	3 (4)	
All the above	2 (2.67)	9 (12)	
Family history of CAD/ACS			0.467
Present	5 (6.67)	3 (4)	
Absent	70 (93.33)	72 (96)	
PTCA	28 (37.33)	47 (62.67)	0.205
CABG	12 (16)	11 (14.67)	

ACS = acute coronary syndrome; CABG = coronary artery bypass graft; CAD = coronary artery disease; DM = diabetes mellitus; HTN = hypertension; PTCA = percutaneous transluminal coronary angioplasty.
* Values for age are presented as mean (SD). All other values are presented as n (%).† Statistically significant difference ($P < 0.05$).

Discussion

MI is associated with significant short- as well as long-term mortality and morbidity.[10] Primarily, MIs are the result of CAD.[11] Approximately 50% of all patients with MI are rehospitalized within 1 year of their index event.[12] Prognosis varies from patient to patient and is dependent primarily on the extent of the infarct, the residual left ventricular function, and whether the patient underwent revascularization. The post-MI treatment plan is intended to improve patient outcomes, prevent hospital readmission, and prevent another MI.[13] American Heart Association guidelines recommend comprehensive care plans that include patient education regarding medication adherence, timely follow-up, dietary interventions, physical activities, and cardiac rehabilitation.[13] Optimal use of evidence-based secondary prevention pharmacotherapy in patients with MI reduces the risk of subsequent cardiovascular events and mortality.[14–18] Studies have demonstrated that a commitment to cardiac rehabilitation; adherence to medication regimens; management of comorbidities; lifestyle modifications, including diet and weight loss if warranted; and routine follow-up with primary caregivers can improve patient outcomes and quality of life.[13] The majority of MI patients in our study were found to be in the age group of 51 to 60 years (36%) in both the study groups. Similar results were found with the study conducted by Mateti et al,[19] where mean age of patients in the control group ranged from 51 to 60 years (30.8%) and in the test group was 61 to 70 years (38.5%). In these study groups, male patients (75.17% in Group A and 86.67% in Group B) were found to be predominant

Table 2
Mean (SD) clinical parameters of the study population.

Parameter	Group A (n = 75)		Group B (n = 75)		*P* value
	Baseline	Follow-up	Baseline	Follow-up	
Systolic blood pressure	131.72 (21.07)	122.80 (8.63)	133.79 (20.49)	127.47 (10.28)	0.0031*
Diastolic blood pressure	84.13(11.64)	81.09 (5.67)	81.20 (5.44)	83.73 (5.88)	0.0069*
RBS	161.38 (10.51)	126.87 (29.13)	177.14 (11.30)	148.31 (47.96)	0.0055*
FBS	142.72 (55.83)	109.63 (29.42)	148.64 (58.98)	121.65 (41.98)	0.0441*
Total cholesterol	224.70 (5.19)	194.716 (28.86)	230.38 (5.20)	210.05 (22.75)	0.0001*
LDL-C	174.89 (4.72)	168.78 (21.47)	183.24 (3.97)	174.89 (18.99)	0.0669
HDL-C	39.28 (0.98)	44.22 (7.05)	41.50 (1.06)	44.85 (7.42)	0.595
Triglyceride	177.66 (12.14)	136.67 (21.8)	168.74 (7.08)	142.78 (25.78)	0.119
VLDL-C	36.85 (2.38)	28.65 (5.71)	36.78 (1.61)	30.11 (14.61)	0.4215

FBS = fasting blood sugar; RBS = resting blood sugar.
* Statistically significant difference between the follow-ups ($P = 0.05$).

Table 3
Rehospitalizations in the study population (n = 75 each group).

Group	n	%
Group A	2	2.67
Group B	5	6.67

compared with female patients (24.83% in Group A and 13.33% in Group B). Comparable results were found by Azmi et al.[20] Most patients in Group A presented with a history of diabetes mellitus (23%), hypertension (20%), or both of these comorbidities (17.33%), whereas a majority of patients in Group B presented with history of both diabetes mellitus and hypertension (24%) followed by diabetes mellitus (18.67%) and hypertension (16%). The percentage of smokers and alcohol users in Group A were 20% and 18%, respectively, and in Group B they were 36% and 18%, respectively. These results are related to the study conducted by Mateti et al.[19] In this study, 37.33% of patients in Group A and 62.67% in Group B underwent percutaneous transluminal coronary angioplasty, whereas 16% in Group A and 14.67% in Group B underwent coronary artery bypass grafting.[20]

This study demonstrated that resting blood sugar ($P > 0.0055$) and fasting blood sugar levels ($P > 0.0441$) were significantly reduced in the pharmacist-counseled group compared with the usual care group over a period of 6 months. These results correlate with those reported by Joel et al,[21] where a statistically significant difference was observed in the mean resting blood sugar ($P > 0.024$) and fasting blood sugar ($P > 0.049$) between intervention and control groups at follow-up. Our results are also consistent with the study conducted by Dhandapani et al,[22] where a statistically significant difference was found in the fasting blood sugar readings of the test group ($P > 0.046$) compared with the control group ($P > 0.870$) at follow-up.

The study also found statistically significant reduction in systolic and diastolic blood pressure in Group A ($P > 0.0031$ and $P > 0.0069$, respectively) compared with Group B. These results are consistent with the reports of Pawar et al,[23] in which counseling provided by clinical pharmacists showed significant reduction of systolic and diastolic blood pressures ($P = 0.0027$).[23]

Reduction in total cholesterol levels was observed in the intervention group compared with the control group ($P > 0.0001$). There were no significant reductions observed in LDL-C ($P > 0.0669$), HDL-C ($P > 0.595$), triglyceride ($P > 0.119$), and VLDL-C ($P > 0.4215$) levels at follow-up. However, there were statistically significant differences seen in each of the study groups from baseline to follow-up. Similar observations were reported by Ho et al,[24] in which pharmacist-led intervention consisting of medication reconciliation, tailoring, and patient education did not show any statistical difference in LDL-C levels ($P = 0.37$) in the year after acute coronary syndrome discharge.[24]

The present study results showed that there were a total of 2 readmissions in Group A (2.67%) and 5 readmissions in Group B (6.67%) during the study period. Gasbarro et al[25] illustrated that 30-day readmission rate was less among patients provided with clinical pharmacist interventions.

In the present study, significant difference was observed in the reported medication adherence measured using MARS between the groups for a period of 6 months. These results correlate with those reported by Spence et al:[26] By having nonadherent patients restart their diabetes mellitus medications, the outpatient clinical pharmacist was able to improve medication adherence ($P = 0.001$). These findings are also consistent with the study conducted by Zerafa et al,[27] where a statistically significant difference was observed between the control and interventional groups in the mean percentage compliance following pharmacist intervention ($P < 0.05$).

Study limitations

This study did have some limitations. First, the time spent by the clinical pharmacist differed in the intervention group due to the structured intervention provided to MI patients compared with the usual care group. Additional limitations included lack of automated device for the BP measurement and short duration of follow-up. The medication adherence was assessed through the subjective measurement by MARS questionnaire, whereas the objective measurement such as examining pharmacy refill record, pill counts, and medication event monitoring systems were not used to

Table 4
Comparison of medication adherence between the study groups (n = 75 in each group).

Subjective medication adherence at follow-up	Group A		Group B		χ^2	*P* value
	n	%	n	%		
Yes	75	100	59	78.67	12.360	0.0001*
No	0	0	16	21.33		

* Statistically significant difference ($P = 0.05$).

Table 5
Comparison of lifestyle modifications between the study populations (n = 75 in each group).

Lifestyle modification	Group A				Group B			
	Baseline	%	Follow-up	%	Baseline	%	Follow-up	%
Smokers	10	13.33	7	9.33	18	24	17	22.67
Alcoholics	9	12.00	6	8.00	9	12	8	10.67

determine the adherence outcomes because this can lead to recall bias and thus decrease the reliability of the adherence data.

Study implications

Based on the study findings, recall bias can be avoided by attempting to use objective outcome assessment along with the MARS questionnaire.

Conclusions

These results suggest that when combined with clinical care, pharmacist counseling may improve the medication adherence and lifestyle modifications by post-MI patients.

Declaration of Competing Interest

The authors have indicated that they have no conflicts of interest regarding the content of this article.

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All authors contributed equally to the study concept, design, and data analysis. S. Sarumathy had full access to the collection of data and was responsible for the integrity and accuracy of the data under the guidance of T. S. Shanmugarajan. Design, conceptualization, and project administration was done by T. S. Shanmugarajan. Analysis and statistical interpretation of data and drafting of the manuscript was done P. Shanmugasundaram.

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