Manipal lifestyle modification score to predict major adverse cardiac events in postcoronary angioplasty patients

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c Abstract

Background: Lifestyle modification (LSM) such as prudent diet, physical activity, avoidance of smoking, and maintaining a healthy weight may considerably decrease the risk for coronary artery disease. Objective: The primary objective of this study was to develop a new LSM scoring system and investigate the correlation between adherence to LSM and incidence of major adverse cardiac events (MACEs) at 12-month follow-up.

Method: A total of 1000 consecutive patients who underwent percutaneous transluminal coronary angioplasty (PTCA) were included in this prospective single-center study. Manipal lifestyle modification score (MLSMS) was developed by using five lifestyle-related factors. Adherence to LSM at the baseline and subsequent follow-ups was determined by using MLSMS. The MACE at 1-, 6-, and 12-month follow-up were analyzed.

Results: There was a significant reduction in overall adherence to LSM ($p < 0.001$) at 12-month follow-up. Nonadherence to LSM [hazard ratio (HR) 0.575; 95% confidence interval (CI) 0.334–0.990; $p < 0.046$] and noncompliance to medication (HR 2.09; 95% CI 1.425–3.072; $p < 0.001$) were independent predictors of MACEs after PTCA. The cumulative MACE was 15.4%, which includes 4.9% of all-cause death, 5.2% of nonfatal myocardial infarction, 2.0% of target lesion revascularization, 1.8% of target vessel revascularization, and 1.3% of stroke at 12 months. The incidence of MACEs at 12 months was significantly ($p = 0.03$) higher in LSM nonadherent compared with LSM adherent patients.

Conclusion: There is an overall reduction in adherence to LSM on successive follow-ups and a significant association between the incidence of MACEs and the lack of adherence to LSM. MLSMS is a simple and effective evaluation tool in predicting MACEs in this group of patients.

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1. Introduction

Coronary artery disease (CAD) is a major cause of morbidity and mortality in India and in the Western world. CAD is the most common type of heart disease, and an estimated 2.4 million deaths every year are attributed to it in India, of which 30% are in urban and 15% from rural population. Hypertension, obesity, hypercholesterolemia, diabetes, and smoking are the major risk factors for CAD. Treatment of CAD is multifactorial and includes medical therapy, interventional/surgical therapy, and lifestyle modification (LSM).

LSM includes physical exercise, appropriate diet, cessation of smoking, and stress management. LSMs are important for both primary and secondary prevention in CAD. LSM has been shown to not only prevent disease but also improve outcomes in patients with CAD after other therapies have been started. Recent guidelines recommend LSM as a part of the treatment strategy in patients being treated for CAD.

LSM is especially important in patients with diagnosed CAD who have undergone surgery/intervention. Many studies have revealed that sustained LSMs have a significant impact on reducing major adverse cardiac events (MACEs) after acute coronary
syndrome (ACS) and coronary intervention. Also, after major events such as ACS and/or percutaneous transluminal coronary angioplasty (PTCA), developing a habit of regular blood pressure (BP) and blood glucose (BG) checkup is also an important modification which is necessary for patient’s life.

Despite this, there is no simple tool available to assess adherence to LSMs and its impact on cardiovascular (CV) outcomes. Also, there have been no studies in the South Indian population linking adherence to LSM and MACES. Therefore, this study was conducted to develop a new tool/scoring system called Manipal lifestyle modification score (MLSMS) to assess adherence to LSM objectively and to correlate it with CV outcomes at the end of 1 year in patients who have undergone PTCA.

2. Methods

This is an observational, cohort study conducted in a tertiary care hospital in Karnataka from January 2015 to December 2017. A total of 1000 consecutive patients aged between 18 and 65 years who underwent PTCA for CAD (ACS or stable angina) during the study period were included. Patients who had undergone PTCA/CABG previously, had a cardiogenic shock at presentation/during hospitalization, left ventricular ejection fraction < 40, chronic kidney disease, chronic liver disease, terminal illness patients with life expectancy < 1 year, psychiatry illness, or pregnant were excluded from the study. A written informed consent was taken from all the study patients. The study protocol was approved by the institutional ethical committee and registered under the Clinical Trial Registry-India (CTR/2017/12/010728).

2.1. Patient population and study design

At index admission, the baseline characteristics such as demographic details, clinical data including a detailed medical history, past history and smoking history, and physical examination including height, weight, and body mass index (BMI) were recorded. Laboratory data including renal function tests (RFTs), Trop-T, N-terminal pro b-type natriuretic peptide (NT-proBNP), details of electrocardiography (ECG), echocardiography (ECHO), treadmill test (TMT) and coronary angiogram (CAG) reports were also recorded at the baseline during the index admission.

Patients underwent PTCA and started on medical therapy as per the existing guidelines. During the index admission, a simple five-point MLSMS questionnaire (see the following section) was administered to each study participants to grade/score their baseline lifestyle details. Details of medication prescribed to study populations on discharge were also recorded. The patient was counseled regarding LSMs, compliance to medicines, and regular follow-up before discharge from the hospital. Patients were requested to follow up at the end of 1, 6, and 12 months after index hospitalization. During each follow-up clinical data, including symptoms, height, weight, BMI as per the World Health Organization norms, physical examination, laboratory parameters such as, fasting blood sugar, glycated hemoglobin (HbA1C), fasting lipid profile, RFT were recorded. If available, ECG, ECHO, Trop-T, and NT-proBNP were also noted. MLSMS was administered at each follow-up to assess adherence to LSMs. Patients were inquired regarding adherence to medications.

2.2. Clinical end points

The primary end point of this study was to determine the 12-month incidence of MACES. MACE includes all-cause death, nonfatal myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR), and stroke.

2.3. Manipal lifestyle modification score

A simple questionnaire for assessment of LSM, called MLSMS, was developed consisting of five questions (Fig. 1). Based on the total LSM score obtained by patients, they were divided into three groups: high (4–5), medium (2–3), and low (0–1) LSM scores. Patients with low and medium scores were considered to be non-adherent to LSM and those with a high score were considered to be adherent.

Internal validation of MLSMS questionnaire was performed by cardiologists, physicians, dieticians, and physiotherapists. For external validation, a pilot study was conducted on 100 patients where data regarding precoronary angioplasty lifestyle factors were collected based on this questionnaire. A reliability analysis was carried out on the perceived task values scale comprising five items. Cronbach’s alpha showed that the questionnaire had acceptable reliability, α = 0.703. After this, the questionnaire was validated on the entire study population both before and after PTCA at each follow-up (Cronbach’s alpha = 0.78).

2.4. Statistical analysis

Continuous variables were presented as mean ± standard deviation and compared using paired t-tests for normally distributed data and Wilcoxon signed-rank test for non-normal data. Categorical variables presented as counts and percentage. The analysis was performed by the chi-square test and Fisher’s exact test. Serial changes in various parameters were assessed at different time points, and comparison was made between the baseline and 1 year follow-up by repeated analysis of variance (ANOVA). The consistency of the LSM questionnaire was measured by Cronbach’s alpha. The impact of LSM, LSM variables, and other variables such as age, smoking, diabetes, hypertension, dyslipidemia, the number of coronary arteries involved, and medication adherence on MACES (death, MI, TLR, TVR, and stroke) was determined using the Cox’s proportional hazards regression model. The results were expressed as hazard ratio (HR) and 95% confidence interval (CI) where appropriate. Time to events between LSM adherent and LSM non-adherent group was summarized and displayed using the cumulative incidence curve by the Kaplan–Meier survival analysis method. All statistical analyses were performed using the Statistical Package for the Social Sciences [SPSS], version 15. A p-value < 0.05 was considered to be statistically significant.

3. Results

3.1. Patient characteristics

The baseline characteristics of patients are summarized in Table 1. At the baseline, the mean MLSMS was only 2. First month mean MLSMS increased to 4 but later decreased over the next two follow-ups [at 6 and 12 months (3.7 and 3.1 respectively), (Fig. 2)]. The proportion of patients with high, medium, and low MLSMS at the baseline and during each follow-up is shown in Fig. 3. Changes in CAD risk factor during the study period are summarized in Table 2. Changes in MLSMS from the baseline to 12-month follow-up were shown in Table 3.

3.2. Clinical outcomes

The MACE observed at 1- and 6-month follow-up was 44 (4.4%) and 116 (11.9%), respectively. Overall MACE (including mortality) at the end of 12-month follow-up was 15.4%, which includes 4.9% of all-cause death, 5.2% of nonfatal MI, 2.0% of TLR, 1.8% of TVR, and 1.3% of stroke. A patient who was adherent to LSM had a lower
Fig. 1. Flowchart of LSM questionnaire in precoronary and postcoronary angioplasty patients. BP, blood pressure; HbA1C, glycated hemoglobin; LSM, lifestyle modification.

Table 1
Baseline characteristics of the study population.

| Characteristics                                      | n = 1000 |
|------------------------------------------------------|----------|
| Age, mean ± SD                                       | 56.2 ± 7.4 |
| Male                                                 | 761 (76.1) |
| History of IHD                                       | 157 (15.7) |
| Smokers/tobacco users                                | 406 (40.6) |
| Mixed diet                                           | 422 (42.2) |
| Hypertension                                         | 556 (55.6) |
| Diabetes mellitus                                    | 422 (42.2) |
| Dyslipidemia                                         | 86 (8.6) |
| SES of study population                              |          |
| Upper class                                          | 68 (6.8) |
| Upper middle class                                   | 77 (7.7) |
| Lower middle class                                   | 209 (20.9) |
| Upper lower class                                    | 196 (19.6) |
| Lower class                                          | 450 (45) |
| Coronary artery disease profile of the study participants |
| STEMI                                                | 549 (54.9) |
| NSTEMI                                               | 253 (25.1) |
| Unstable angina                                      | 147 (14.7) |
| Stable angina                                        | 51 (5.1) |
| Normal LVEF                                           | 862 (86.2) |
| Mild LV dysfunction                                  | 132 (13.8) |
| Thrombolysed                                         | 20 (2.0) |
| Primary PCI                                          | 424 (42.4) |
| SVD                                                  | 465 (46.5) |
| DVD                                                  | 369 (36.9) |
| TVD                                                  | 166 (16.6) |
| LAD                                                  | 500 (50) |
| Baseline medicine prescription                       | Number (%) |
| Aspirin                                              | 998 (99.8) |
| P2Y12 inhibitor                                      | 1000 (100) |
| Ticagrelor                                           | 557 (55.7) |
| Clopidogrel                                          | 443 (44.3) |
| Statins                                              | 992 (99.2) |

SD, standard deviation; IHD, ischemic heart disease; STEMI, ST-elevation myocardial infarction; NSTEMI, non–ST-elevation myocardial infarction; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; SVD, single-vessel disease; DVD, double-vessel disease; TVD, triple-vessel disease; LAD, left anterior descending artery; SES, socioeconomic status.

Fig. 2. Mean LSM score at the baseline and follow-ups. LSM, lifestyle modification; PTCA, percutaneous transluminal coronary angioplasty.

Fig. 3. Proportion of subjects with various LSM categories at different time points. LSM, lifestyle modification; PTCA, percutaneous transluminal coronary angioplasty.
Table 2
Changes in risk factors.

| Risk factors      | Baseline (n = 1000) | 1 month (n = 999) | 6 months (n = 985) | 12 months (n = 975) | p value |
|-------------------|---------------------|------------------|-------------------|---------------------|---------|
| BMI, kg/cm²       | 23.8 ± 4.0          | 23.0 ± 4.1       | 23.4 ± 4.1        | 23.8 ± 4.2          | 0.94    |
| SBP, mmHg         | 132.5 ± 21.2        | 131.2 ± 20.4     | 132.5 ± 20.3      | 134.2 ± 21.5        | 0.08    |
| DBP, mmHg         | 82.2 ± 12.0         | 81.9 ± 10.4      | 82.5 ± 10.0       | 82.9 ± 9.4          | 0.17    |
| FBS, mg/dL        | 144.6 ± 61.8        | 127.6 ± 58.7     | 123.9 ± 46.1      | 124.4 ± 46.4        | 0.001   |
| HbA1C, %          | 7.2 ± 2.2           | 7.2 ± 2.2        | 7.5 ± 1.6         | 7.5 ± 1.8           | 0.001   |
| TC, mg/dL         | 171 ± 47.9          | 148.6 ± 41.2     | 148.6 ± 41.2      | 150.5 ± 39.5        | 0.001   |
| TG, mg/dL         | 136.8 ± 73.7        | 132.0 ± 61.8     | 132.3 ± 72        | 135.5 ± 65.5        | 0.69    |
| LDL, mg/dL        | 106.9 ± 40.2        | 88.9 ± 37.3      | 85.5 ± 36.1       | 83.9 ± 34.2         | 0.001   |
| HDL, mg/dL        | 38.4 ± 12.2         | 40.2 ± 11.7      | 41.9 ± 11.2       | 43.6 ± 11.4         | 0.001   |
| VLDL, mg/dL       | 28.8 ± 19.2         | 26.9 ± 16.05     | 25.3 ± 20.0       | 24.4 ± 22.3         | 0.001   |
| NYHA classification| I 125               | 981              | 953               | 954                 | 0.001   |
|                  | II 521              | 13               | 21                | 12                  |         |
|                  | III 282             | 4                | 9                 | 4                   |         |
|                  | IV 72               | 1                | 2                 | 5                   |         |

BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBS, fasting blood sugar; HbA1C, glycated hemoglobin; TC, total cholesterol; LDL, low density lipoprotein; HDL, high density lipoprotein; TG, triglyceride; VLDL, very low-density lipoprotein; NYHA, New York Heart Association.

*p-value comparisons are made between the baseline and 12-month follow-up. Dahiru T. P-value, a true test of statistical significance? A cautionary note. Annals of Ibadan postgraduate medicine. 2008;6(1):21-6.

Table 3
Changes in MLSMS from the baseline to 12-month follow-up.

| Changes in MLSMS | Baseline (n = 1000) | 12-month follow-up (n = 975) | p value |
|------------------|---------------------|-----------------------------|---------|
| Diet control     | 331 (33.1)          | 600 (64.3)                  | <0.05   |
| Not smoking/not using tobacco | 593 (59.3)          | 765 (81.9)                  | <0.05   |
| Regular blood pressure checkup | 464 (46.4)          | 638 (68.38)                 | <0.05   |
| Regular blood sugar checkup | 378 (37.8)          | 673 (72.13)                 | <0.05   |
| Regular physical exercise | 244 (24.4)          | 487 (52.19)                 | <0.05   |

*p-value<0.05 was considered as statistically significant. Dahiru T. P-value, a true test of statistical significance? A cautionary note. Annals of Ibadan postgraduate medicine. 2008;6(1):21-6.

MLSMS, Manipal lifestyle modification score.

Table 4
Cardiac events during 12-month follow-up.

| Events            | 1-month follow-up (n = 999) (%) | 6-month follow-up (n = 985) (%) | 12-month follow-up (n = 975) (%) |
|-------------------|---------------------------------|---------------------------------|---------------------------------|
| All-cause death   | 22 (2.2)                        | 40 (4.1)                        | 46 (4.9)                        |
| Cardiac death     | 18 (1.8)                        | 29 (2.9)                        | 33 (3.5)                        |
| Noncardiac death  | 4 (0.4)                         | 11 (1.1)                        | 13 (1.3)                        |
| Nonfatal MI       | 11 (1.1)                        | 40 (4.1)                        | 49 (5.2)                        |
| TLR               | 5 (0.5)                         | 16 (1.6)                        | 19 (2.0)                        |
| TVR               | 0 (0.0)                         | 10 (1.0)                        | 17 (1.8)                        |
| Stroke            | 6 (0.6)                         | 10 (1.0)                        | 13 (1.3)                        |
| MACE              | 44 (4.4)                        | 116 (11.9)                      | 144 (15.4)                      |
| 12-month follow-up| LSM nonadherence (n = 684)      | LSM adherence (n = 291)         | p-value                         |
| MACE              | 116 (16.9%)                     | 28 (11.25)                      | 0.03                            |

MACE, major adverse cardiac event; MI, myocardial infarction; TLR, target lesion revascularization; TVR, target vessel revascularization; LSM, lifestyle modification.

*p-value<0.05 was considered statistically significant. Dahiru T. P-value, a true test of statistical significance? A cautionary note. Annals of Ibadan postgraduate medicine. 2008;6(1):21-6.

4. Discussion

LSM is an important component of both the prevention and treatment of ischemic heart disease/CAD. LSM has been shown to affect outcomes after PTCA.^{11} Diet control, weight control, cessation of smoking/tobacco use, and adherence to regular physical exercise solely depend on patient interest.^{16,19} However, optimum control of BP and BG purely depends on pharmacological therapy; it depends on how physician plans the treatment and how much patients adhere to the prescribed medication.^{14,15} Several studies have shown that there is an association between noncompliance to antihypertensive and antidiabetic medicine with MACEs. Titration of antihypertensive and antidiabetic treatment was performed by the cardiologist/physician on the basis of accurate BP and BG values as important as the initiation of treatment for hypertension and diabetes mellitus. However, some patients are irregular with BP and BG checkup. It is advised to check the BP regularly at least once in 4 weeks at a clinic/hospital visit or BP checkup at home at least once in 2 weeks.^{20} and BG checkup should be performed at least once in 4 weeks or HbA1C checkup once in 3 months for those who are on oral antihyperglycemic agents. In patients who are on insulin with poor BG control, it is recommended to check BG at least two times/day (after and before bedtime); for stable oral hypoglycemic agents (OHA) patients, it is advised to check fasting blood glucose (FBG) once in 4 weeks and nondiabetic patients, once in 6 months.^{21,22} Although dietary changes, cessation of smoking/tobacco use, and...
physical exercise are considered to be a component of LSM, 23,24–28 an attitude/habit of regular BP and BG monitoring should also be included. MLSMS includes all these components.

In this study, we found that after PTCA, adherence to LSMs is high during the initial period of follow-up, but by the end of 1 year, there is a significant decrease in adherence (4.1 ± 1.1 vs. 3.1 ± 1.6, p < 0.001). In a study by Sadeghzadeh et al., similar findings were seen.24 Therefore, it is important to reinforce the significance of LSM to patients on every follow-up. There were favorable changes in many of the risk factors of the CAD during our study; however, it would not be possible to attribute it entirely to LSM because medication also has a major role to play.

Patients who were adherent to LSM (MLSMS 4–5) were found to have a lesser MACE at 12-month follow-up (11.2%) compared with those who were nonadherent (16.9%), even on multivariate analysis, after adjusting for all major confounding factors, including drug noncompliance. Nonadherence to LSM was still associated with an increased MACE rate (HR 0.575; 95% CI 0.334–0.990; p < 0.046). These results are similar to the results of Stewart et al., Sadeghzadeh et al. and Akesson A, et al. 12,24,29

In our study, we also found drug noncompliance as an important predictor of MACEs. This was comparable to an earlier study conducted by Kappagoda et al. Therefore, it is important to emphasize the importance of LSM and drug compliance to patients at each hospital visit especially after PTCA to improve long-term outcomes.

4.1. Study limitation

It is a single-center study. Although the cohort study design might be a limitation, because LSMs such as continuation of smoking/tobacco use, irregular BP checkup, irregular BG checkup, and irregular physical exercise remains relatively constant from the beginning, the strong association with MACEs makes it possible to extrapolate this association to the beginning of the adverse cardiac event itself.

5. Conclusion

 MLSMS is a simple and effective evaluation tool to predict outcomes after PTCA. Adherence to LSM decreases over time, and therefore, it is important to emphasize its importance during each follow-up.

Table 5
Adjusted Cox and unadjusted Cox proportional analyses: MACE among different variables.

| Variable                        | Unadjusted HR (95% CI) | p-value | Adjusted HR (95% CI) | p-value |
|---------------------------------|------------------------|---------|----------------------|---------|
| Age                             | 1.008 (0.985–1.031)    | 0.498   | 1.006 (0.982–1.031)  | 0.608   |
| Male gender (vs female gender)  | 0.925 (0.628–1.362)    | 0.639   | 0.893 (0.592–1.349)  | 0.591   |
| Smokers (vs nonsmokers)         | 0.981 (0.700–1.373)    | 0.918   | 0.992 (0.700–1.404)  | 0.963   |
| Alcoholic (vs nonalcoholic)     | 1.069 (0.883–1.294)    | 0.493   | 1.082 (0.719–1.630)  | 0.705   |
| Hypertensive (vs nonhypertensive)| 1.049 (0.888–1.238)   | 0.577   | 1.082 (0.744–1.574)  | 0.678   |
| Diabetic (vs nondiabetic)       | 1.038 (0.877–1.229)    | 0.633   | 1.222 (0.789–1.892)  | 0.37    |
| Dyslipidemia (vs nondyslipidemia)| 1.143 (0.600–2.177)   | 0.684   | 1.053 (0.544–2.039)  | 0.878   |
| STEMI (vs non-STEMI)            | 1.084 (0.769–1.529)    | 0.644   | 0.998 (0.435–2.293)  | 0.997   |
| NSTEMI (vs non-NSTEMI)          | 0.997 (0.679–1.465)    | 0.989   | 0.832 (0.360–1.919)  | 0.666   |
| NYHA class                      | 0.606 (0.364–1.009)    | 0.05    | 0.607 (0.237–1.552)  | 0.297   |
| SVD (non-SVD)                   | 1.202 (0.732–1.974)    | 0.467   | 0.969 (0.379–2.480)  | 0.948   |
| Fasting blood sugar             | 0.999 (0.996–1.001)    | 0.394   | 0.998 (0.994–1.001)  | 0.225   |
| HbA1c                           | 1.031 (0.952–1.116)    | 0.455   | 1.121 (1.004–1.251)  | 0.043   |
| Total cholesterol               | 0.995 (0.992–0.999)    | 0.009   | 0.997 (0.988–1.005)  | 0.458   |
| Triglyceride                    | 0.999 (0.997–1.002)    | 0.59    | 1.001 (0.998–1.004)  | 0.432   |
| LDL                             | 0.994 (0.990–0.998)    | 0.004   | 0.997 (0.987–1.006)  | 0.513   |
| HDL                             | 1.005 (0.992–1.018)    | 0.474   | 1.010 (0.996–1.023)  | 0.157   |
| NYHA class                      | 1.125 (0.908–1.395)    | 0.282   | 1.180 (0.931–1.491)  | 0.171   |
| Irregular diet control (regular diet control) | 1.135 (0.797–1.616)  | 0.483   | 1.033 (0.697–1.529)  | 0.873   |
| Irregular BP checkup (regular BP checkup) | 0.68 (0.490) | 0.007   | 3.82 (1.4310.909)  | 0.007   |
| Irregular BG checkup (regular BG checkup) | 0.55 (0.400, 0.77) | <0.001  | 0.55 (0.40, 0.77)  | <0.001  |
| Continue to smoke/tobacco use (not smoking/not using tobacco) | 1.47 (1.1, 1.97) | 0.009  | 1.47 (1.1, 1.97)  | 0.009  |
| Irregular physical exercise (regular physical exercise) | 0.60 (0.48, 0.99) | 0.04 | 4.60 (1.03–20.49)  | 0.04   |
| Nondrug compliance (drug compliance) | 2.270 (1.570–3.282) | <0.001  | 2.092 (1.425–3.072)  | <0.001  |
| Non-LSM adherence (LSM adherence) | 0.595 (0.390–0.905) | 0.015  | 0.573 (0.334–0.990)  | 0.046  |

MACE, major adverse cardiac event; STEMI, ST-elevation myocardial infarction; NSTEMI, non-ST-elevation myocardial infarction; UA, unstable angina; SA, stable angina; SVD, single vessel disease; DVD, double vessel disease; TVD, triple vessel disease; SBP, systolic blood pressure; DBP, diastolic blood pressure; HbA1C, glycated hemoglobin; LDL, low-density lipoprotein; HDL, high-density lipoprotein; NYHA, New York Heart Association; BP, blood pressure; BG, blood glucose.

Fig. 4. Time-to-event curve by the Kaplan–Meier method. LSM, lifestyle modification.
Conflict of interest

All authors have none to declare.

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