A Study to Determine Impact of Non-Compliance to Secondary Prophylaxis On Survivors of Acute Myocardial Infarction Post Discharge

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ABSTRACT

Background: Coronary artery disease is the one of the leading cause of mortality and morbidity in India[1] and has huge economic burden. Non-adherence to cardiovascular medications is pandemic and a leading risk factor for the treatment failures and poor outcomes. This study was undertaken with to determine if any relation exists between degrees of adherence to pharmacotherapy amongst survivors of acute myocardial infarction to their outcome at 6 month follow up.

Methods: This study was carried out in the Department of Medicine, M.G.M. Medical College and M.Y. Hospital Indore from November 2013 to October 2014. We included 100 consecutive patients of myocardial infarction admitted to intensive coronary care unit. All patients or legally acceptable representative provided written informed consent for participation. The research protocol and informed consent form was approved by The Institutional Review Board.

Results: All 100 patients were followed out of 67 patients who were compliant to prescribed therapy, 78% had no complication while 22% developed various complications over a period of 6 month follow up. Out of 33 patients who were noncompliant, 37% had no complications while 63% developed various complications. The patients who were noncompliant to prescribed therapy had more adverse clinical events in comparison to those who were complaint to prescribed therapy.

Conclusions: Patients who were non adherent to prescribed pharmacotherapy had three times more adverse cardiovascular outcomes in comparison to those who were adherent to prescribed therapy. Adherence to the secondary prophylaxis is crucial to prevent adverse cardiovascular complications and needs to have multimodal approach to tackle non adherence.

Keywords: Secondary Prophylaxis, Myocardial Infarction, Non Adherence Rate, Impact, Compliance.

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INTRODUCTION

Coronary artery disease is the one of the leading cause of mortality and morbidity in India[1] and has huge economic burden.[1] Non-adherence to cardiovascular medications is pandemic and a leading risk factor for the treatment failures and poor outcomes.[2] After acute myocardial infarction multidrug pharmacotherapy is widely recognized as crucial to the reduce risk of a subsequent acute myocardial infarction and other cardiac problems such as heart failure. Poor adherence to lipid-lowering and antiplatelet therapies is associated with an increased risk of adverse cardiovascular outcomes including myocardial infarction, stroke, and death, stent recipients who prematurely discontinue clopidogrel also have an increased rate of stent thrombosis.

Post-MI patients who discontinue their prescribed aspirin, statin, and beta-blocker are more than three times more likely to die than patients who remain adherent[3] and atleast a third of all medication-related hospital admissions are caused by poor medication adherence.

METHODS

This study was carried out in the Department of Medicine, M.G.M. Medical College and M.Y. Hospital Indore from November 2013 to October 2014. We included 100 consecutive patients of myocardial infarction admitted to intensive coronary care unit who fulfills inclusion criteria and exclusion criteria. All patients or legally acceptable representative provided written informed consent for participation. The research protocol and informed consent form (ICF) was approved by The Institutional Review Board.

Patient's data was collected during hospital stay and at the time of

discharge and on follow up after 1 month, 3 month and 6 month using a standard Case Report Form. Data collected in the form of Baseline Characteristics, Literacy, Family income, Type of myocardial infarction, Risk Factors for myocardial infarction, routine investigations like complete blood count, renal function test, serum electrolyte, lipid profile, ECG, cardiac biomarkers ,drug compliance and complications if any including morbidity in form of development of reinfarction, heart failure, stroke or hospital admission due to other causes as well as mortality at post discharge follow up of patients was noted. On the data obtained from patients statistical analysis was applied. The basic characteristic of patients, degree of noncompliance among different subgroups/different drugs, important determinants of noncompliance was measured. Using the multivariate analysis, the correlation between therapy noncompliance and its effect on clinical outcome was measured.

Table 1: Gender of patients and their therapy compliance

Gender	Total no of Patients	Compliant	Noncompliant
Male	79	56 (71%)	23 (29%)
Female	21	11 (52%)	10 (48%)

Table 2: Age group of patients and therapy compliance

Age group (in years)	Total no of pt.	Compliant	Noncompliant
<40	15	14 (93%)	1 (7%)
41-50	18	13 (72%)	5 (28%)
51-60	28	18 (64%)	10 (36%)
61-70	23	13 (57%)	10 (43%)
71-80	12	7 (58%)	5 (42%)
>80	4	2 (50%)	2 (50%)

Table 3: Residence of patients and therapy compliance

Residence	Total no. of patients	Compliant	Noncompliant
Urban	66	48 (73%)	18 (27%)
Rural	34	19 (54%)	15 (46%)

Table 4: Education status of patients and therapy compliance

Education status	Total no. of Patients	Compliant	Noncompliant
Illiterate	31	13 (42%)	18 (58%)
Primary	27	20 (74%)	7 (26%)
Middle	17	10 (59%)	7 (41%)
High school	12	11 (92%)	1 (8%)
Higher secondary	12	12 (100%)	0 (0%)
Graduate or more	1	1 (100%)	0 (0%)

Table 5: Family income and therapy compliance

Family Income (Rs/month)	Total no. of Patients	Compliant	Noncompliant
<5000	5	1 (20%)	4 (80%)
5000-10000	51	29 (57%)	22 (43%)
10001-20000	40	33 (83%)	7 (17%)
>20000	4	4 (100%)	0 (0%)
Total	100	67 (67%)	33(33%)

Table 6: Final outcome of therapy compliance or noncompliance

Final outcome	Compliant	Noncompliant
Total no of Patients	67	33
No complication	52 (78%)	12 (37%)
Re-infarction	1 (1.5%)	4 (12%)
Heart failure	5 (7.5%)	8 (24%)
Stroke	1 (1.5%)	2 (6%)
Death	7 (10%)	3 (9%)
Other complication	1 (1.5%)	4 (12%)

RESULTS

All 100 patients were followed, out of 79 male patients 56 (71%) were having good compliance while 23 (29%) were non-compliant. Amongst 21 females 11 (52%) were compliant while 10 (48%) were non-compliant. The association between gender of patient and therapy compliance was statistically non-significant (p = 0.109).

14 (93%) out of 15 patients in age group <40 years were compliant to prescribed therapy while 13 (72%) out of 18 in age group 41-50 years were compliant. In age group 51-60 years 18 (64%) out of 28 were compliant while 13 (57%) out 23 patients in age group 61-70 years were compliant. 7 (58%) out of 12 patients in age group 71-80 years were compliant while 2 (50%) out of 4 patient over 80 years age were compliant. The effect of age on therapy compliance was not statistically significant (p = 0.214).

66 patients had urban residence, out of which 48 (73%) were compliant while 18 (27%) were noncompliant. 34 patients had rural residence, out of which 19 (54%) were compliant while 15 (46%) were noncompliant. There was no statistically significant association between residence of patient with their therapy compliance (p = 0.090). Only 13 (42%) out of 31 patients who were illiterate were compliant to therapy compared with 20 (74%) out of 27 patients educated up to primary level, 10 (59%) out of 17 educated up to middle school and 11 (92%) out of 12 educated up to high school. Out of 12 patients educated up to higher secondary level and 1 patient who was graduate, all were having good compliance to prescribed therapy. The association between educational status of patients and their therapy compliance was statistically significant (p = 0.001).

Only 1 (20%) out of 5 patients whose family income was below 5000 rupees/month was compliant in comparison to 29 (57%) out of 51 and 33 (83%) out of 40 in patients having 5000-10000 and 10001-20000 rupees/month income. 4 patients who were having family income >20000 rupees/month, all had good compliance to therapy. The association between family income of patients with their therapy compliance was statistically significant (p = 0.003).

Final Outcome of Therapy Compliance or Noncompliance

Out of 67 patients who were compliant to prescribed therapy, 78% had no complication while 22% developed complications over a period of 6 month follow up, in form of 1.5% had re-infarction, 7.5% developed heart failure, 1.5% developed stroke, 1.5% had other complication such as angina or requirement for hospitalization and 10% died during period of follow up. Out of 33 patients who were noncompliant, 37% had no complications while 63% had complications in form of, 12% had reinfarction, 24% developed heart failure, 6% developed stroke, 9% died during period of follow up and 12% had other complication such as angina or requirement for hospitalization. The patients who were compliant to therapy had less adverse clinical events in comparison to those who were noncompliant (p < 0.001).

DISCUSSION

In previous studies of the patients of Myocardial infarction in India the mean age of patients were 57.5 years (Xavier et al 2008[4]), 60.4 years (Mohanan et al 2012[5]). In our study Mean age of patients was 57.68 years.

In our study majority of patients (51%) were in age group 51 to 70 years of age. In study by Xavier et al[4] 56.7% while in study by Mohanan et al[5] 57.2% of patients were in age group 51-70 years.

Men are more likely to have a myocardial infarction than women; this may be due to differences in risk factors such as smoking and tobacco chewing which are more prevalent among men in India in comparison to women.

In our study there were 79% males in comparison to 21% females. Previous studies have reported similar male to female proportion in patients of myocardial infarction as 76.4% male and 23.6% females (Xavier et al 2008[4]), 77.4% male and 22.6% females (Mohanan et al 2012[5]).

In study by Mohanan et al[5] 19.7% patients were illiterate, 20% patients had received primary education (class 1-7), 40.7% patients had received secondary education (class 8-11) and 19.6% patients were educated up to 12th standard or more.

In our study Amongst 100 patients, 31% patients were illiterate while 27% were educated up to primary and 17% up to middle school. 12% patients were educated up to high school, 12% up to higher secondary and 1 patient was graduate

In study by Xavier et al[4] among 20468 patients 37.7% were known Hypertensive, 30.4% were Diabetic and 40.4% patients were having current or past history of smoking. In study by Mohanan et al[5] amongst 25748 patients history of Hypertension was present in 48.8% patients, history of Diabetes in 37.6% patients while smoking in 34.4% patients.

In our study Hypertension was present in 37% patients, Diabetes in 30% patients and smoking was present in 50% patients as risk factor.

Out of 67 patients who were compliant to prescribed therapy, 78% had no complication while 22% developed various complications over a period of 6 month follow up, in form of 1.5% had re-infarction, 7.5% developed heart failure, 1.5% developed stroke, 1.5% had other complication such as angina or requirement for hospitalization and 10% died during period of follow up.

Out of 33 patients who were noncompliant, 37% had no complications while 63% developed various complications in form of, 12% had reinfarction, 24% developed heart failure, 6% developed stroke, 9% died during period of follow up and 12% had other complication such as angina or requirement for hospitalization. The patients who were noncompliant to prescribed therapy had more adverse clinical events in comparison to those who were complaint to prescribed therapy (p < 0.001).

Ho PM et al[6] found that In the chronic coronary artery disease setting, nonadherence to cardio protective medications (beta blockers, statins, and/or angiotensin-converting enzyme inhibitors) was associated with a 10% to 40% relative increase in risk of cardiovascular hospitalizations and a 50% to 80% relative increase in risk of mortality.

Rasmussen et al[7] evaluated the relationship between mortality and adherence to essential cardiac medications (statins and beta-blocker) after a myocardial infarction. They found that patients who were least adherent to statins were 25% more likely to die than patients who were most adherent. Intermediate adherers were 12% more likely to die than the best adherers.

McDermott and colleagues[8] reviewed the literature on cardiovascular disease that reported admission to hospital and mortality according to adherence groups. They found that seven of 12 studies had a significant association between adherence and outcomes. Three studies showed that adherence to placebo was associated with improved outcomes, suggesting that adherent

behavior may be a marker of better prognosis or confers a protective effect on patients with coronary heart disease.

DiMatteo and colleagues[9] analyzed sixty-three studies assessing patient adherence and outcomes of medical treatment; they found that the risk of a poor health outcome was 26% lower in participants with good adherence in comparison to those who were non adherent.

Limitations of our study were small sample size and indirect methods of adherence assessment include patient questionnaires, self-reports, pill counts, rate of prescription refills, assessment of the patient's clinical response and mostly follow up was done telephonically.

CONCLUSION

Patients who were non-adherent to prescribed therapy had three times more adverse cardiovascular outcomes comparison to those who were adherent to prescribed therapy. Adherence to the secondary prophylaxis is most crucial to prevent adverse cardiovascular complications and needs to have multimodal approach to tackle non adherence.

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