A Study to Find Prevalence of Non-Adherence to Secondary Prophylaxis Amongst Patients of Acute Myocardial Infarction and Barriers to the Compliance

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ABSTRACT

Background: Secondary prevention is an essential part of the contemporary care of the patient with cardiovascular disease (CVD). Patients with established coronary heart disease (CHD) have a high risk of subsequent cardiovascular events including myocardial infarction (MI), stroke and death from cardiovascular disease (CVD). Non adherence to secondary prophylaxis to prescribed pharmacotherapy is common amongst patients of acute myocardial infarction post discharge. This study was undertaken to find out prevalence of non-adherence to secondary prophylaxis amongst the survivors of acute myocardial infarction and barriers to the compliance.

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 up at 1 month and 6 month post discharge. Overall non-compliance at 1 month and 6 month follow up was 20% and 37% respectively. All patients were prescribed lipid lowering agents (statins) at discharge, while antiplatelet agents and ACE inhibitors/ARBs were prescribed in 99 and beta blockers were prescribed in 94 patients at discharge.81% and 66% patients were compliant while 19% and 34% were noncompliant to antiplatelet agents at 1month and 6month respectively. 70% and 59% patients were compliant while 30% and 41% patients were noncompliant to statins at 1month and 6month respectively. 77% and 63% patients were compliant, while 23% and 37% patients were non-compliant to beta blockers at 1 month and 6 month respectively. 20% and 35% were noncompliant at 1 month and 6 month respectively with ACE inhibitors or ARBs. Health system related, side effects and complexity of regimen and socioeconomic factors were main reasons for therapy noncompliance

Conclusions: Over all non-adherence to secondary prophylaxis therapy in survivors of acute myocardial infarction was 23% and 37% at 1 month and 6 month respectively. Adherence to prescribed therapy was high during initial follow up period following index hospitalization for cardiac events and declined significantly over time. Health system related (Inadequate health care resources, lack of motivation and proper communication by health care providers); side effects and complexity of regimen and socioeconomic factors were main reasons for therapy noncompliance.

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

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INTRODUCTION

More than 60% of the global burden of coronary heart disease occurs in developing countries.[1] Coronary artery disease is one of the most important causes of mortality and morbidity in India.[2] It also leads to massive economic burden.[2] Secondary prophylaxis in form of multidrug pharmacotherapy is essential to reduce further adverse cardiac outcomes.[3,4] Non-compliance to secondary prophylaxis therapy is widely prevalent and has various determinants.[5-9]

We aimed to find out prevalence of non-adherence to secondary prophylaxis amongst the survivors of acute myocardial infarction post discharge and barriers to the compliance at M.G.M. Medical College, Indore, Madhya Pradesh, India.

METHODS

This study was carried out in the Department of Medicine, MGM 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.

With considering all the inclusion and exclusion criteria, Patients' data were collected including demographic details, 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 etc. during hospital stay, at the time of discharge and during subsequent follow up using a standard Case Report Form. Patients were called personally or contacted telephonically at 1 month and 6 month interval post discharge to know the adherence/compliance to secondary prophylaxis therapy. The various determinants for non-compliance or poor compliance to secondary prophylaxis therapy were recorded. Collected data was assessed using statistical analysis.

RESULTS

Baseline Characteristics

Total 100 patients participated in the study, 79% (79) were male while 21% (21) were female. Study participants were 28-100 years old (mean 57.68 years), highest proportion (51%) of patients were 51-70 years old. 66% (66) had urban while 34% (34) had rural residence. 31% (31) patients were illiterate, 27% (27) patients were educated up to primary standard, while 42% (42) patients were educated more than primary standard. Majority of patients (91%) had family income in 5000-20000 rupees/month range, while 5% (5) were having family income below, and 4% (4) were having family income above this range.

Compliance during Follow Up & Reasons for Non-compliance
At 1 Month Follow Up

All 100 patients were followed up at 1 month interval post discharge. All patients were prescribed lipid lowering agents (statins) at discharge, while antiplatelet agents and ACE inhibitors/ARBs were prescribed in 99 and beta blockers were prescribed in 94 patients at discharge. 81% patients were compliant to antiplatelet agents, while 19% were noncompliant. 70% patients were compliant to statins while 30% patients were noncompliant. 77% patients were compliant to beta blockers, while 23% patients were non-compliant. 80% patients were compliant to ACE inhibitors or ARBs while 20% were noncompliant.

Health system related reasons (such as lack of motivation, inadequate healthcare resources, poor communication between healthcare providers and patients or their caregivers etc.) were the most common reasons responsible for noncompliance for all classes of drugs. They were responsible for 60%-69% cases of noncompliance among different classes of drugs (69%, 60%, 64% and 65% cases of noncompliance for antiplatelet agents, statins, beta blockers and ACE inhibitors/ARBs respectively).

Therapy related factors such as side effects of medications, complexity of regimen etc. were the second most common reasons for noncompliance, being responsible for 13%-18% cases of noncompliance among different drug classes (16%, 13%, 18%

and 15% cases of noncompliance for antiplatelet agents, statins, beta blockers and ACE inhibitors/ARBs respectively).

Socioeconomic factors such as low medical literacy, poor social support (5%-20%), condition related factors such as asymptomatic nature of disease, coexisting mental illness (3%-5%) and patients related factors such as psychological/behavioral traits (3%-5%) were other reasons for noncompliance.

Table 1: Gender distribution

Gender	No. of Patients
Male	79 (79%)
Female	21 (21%)
Total	100

Table 2: Age Distribution

Age Group (Years)	No. of Patients
<40	15 (15%)
41-50	18 (18%)
51-60	28 (28%)
61-70	23 (23%)
71-80	12 (12%)
>80	4 (4%)
Total	100

Table 3: Educational status of patients

Educational Status	No. of Patients
Illiterate	31 (31%)
Primary	27 (27%)
Middle	17 (17%)
High School	12 (12%)
Higher Secondary	12 (12%)
Graduate or more	1 (1%)
Total	100

Table 4: Family income of patients

Income Group (Family income in Rupees/month)	No. of Patients
<5000	5 (5%)
5000-9999	51 (51%)
10000-20000	40 (40%)
>20000	4 (4%)
Total	100

At 6 Month Follow Up

71 patients were followed up and assessed for compliance at 6 month interval post discharge (because out of total 100 patients enrolled in study few died and few had lost of follow up). All 71 patients were prescribed antiplatelet agents and lipid lowering agents (statins), while 70 patients were prescribed ACE inhibitors/ARBs and beta blockers at their previous follow up.

66% patients were compliant to antiplatelet agents, while 34% were noncompliant. 59% patients were compliant to statins while 41% patients were noncompliant. 63% patients were compliant to beta blockers, while 37% patients were non-compliant. 65% patients were compliant to ACE inhibitors or ARBs while 35% were noncompliant.

Health system related reasons (such as lack of motivation, inadequate healthcare resources, poor communication between healthcare providers and patients or their caregivers etc.) were the

most common reasons responsible for noncompliance for all classes of drugs. They were responsible for 58%-67% cases of noncompliance among different classes of drugs (63%, 62%, 58% and 67% cases of noncompliance for antiplatelet agents, statins, beta blockers and ACE inhibitors/ARBs respectively).

Therapy related factors such as side effects of medications, complexity of regimen etc. were the second most common reasons for noncompliance, being responsible for 14%-19% cases

0f noncompliance among different drug classes (17%, 14%, 19% and 17% cases of noncompliance for antiplatelet agents, statins, beta blockers and ACE inhibitors/ARBs respectively).

Socioeconomic factors such as low medical literacy, poor social support (4%-14%), condition related factors such as asymptomatic nature of disease, coexisting mental illness (8%) and patients related factors such as psychological/behavioral traits (4%) were other reasons for noncompliance.

Table 5: Compliance at 1 month follow up

Treatment	Total no. of patients prescribed treatment	No. of patients Compliant	No. of patients Noncompliant
Antiplatelet agents	99	80 (81%)	19 (19%)
Lipid lowering agents (Statins)	100	70 (70%)	30 (30%)
Beta blockers	94	72 (77%)	22 (23%)
ACE inhibitors/ARBs	99	79 (80%)	20 (20%)

Table 6: Reasons for noncompliance at 1 month follow up

Categories of noncompliance	Reasons for noncompliance	No. of noncompliant patients			
		Antiplatelet Agents	Lipid lowering Agents (Statins)	Beta blockers	ACEI/ ARBs
Health system	Lack of motivation, Inadequate healthcare resources, Poor communication	13 (69%)	18 (60%)	14 (64%)	13 (65%)
Condition	Asymptomatic nature of Disease, Mental health disorders	1 (5%)	1 (3%)	1 (4%)	1 (5%)
Patient	Psychological/ behavioral	1 (5%)	1 (3%)	1 (4%)	1 (5%)
Therapy	Side effect of medication, Complexity of regimen	3 (16%)	4 (14%)	2 (9%)	3 (15%)
Socioeconomic	Low medical literacy, Poor social support	1 (5%)	6 (20%)	4 (19%)	2 (10%)
Total Noncompliant patients		19	30	22	20
Total Compliant patients		80	70	72	79

Table 7: Compliance at 6 month follow up

Treatment	No. of patients prescribed treatment	No. of patients compliant	No. of patients noncompliant
Antiplatelet agents	71	47 (66%)	24 (34%)
Lipid lowering agents (Statins)	71	42 (59%)	29 (41%)
Beta blockers	70	44 (63%)	26 (37%)
ACE inhibitors/ARBs	70	46 (65%)	24 (35%)

Table 8: Reasons for noncompliance at 6 month follow up

Categories of noncompliance	Reasons for noncompliance	No. of noncompliant patients			
		Antiplatelet Agents	Lipid lowering Agents (Statins)	Beta blockers	ACEI/ ARBs
Health system	Lack of motivation, Inadequate health care resources, Poor communication	15 (63%)	18 (62%)	15 (58%)	16 (67%)
Condition	Asymptomatic nature of Disease, Mental health disorders	2 (8%)	2 (7%)	2 (8%)	2 (8%)
Patient	Psychological/ behavioral	1 (4%)	1 (3%)	1 (3%)	1 (4%)
Therapy	Side effect of medication, Complexity of regimen	4 (17%)	4 (14%)	5 (19%)	4 (17%)
Socioeconomic	Low medical literacy, Poor social support	2 (8%)	4 (14%)	3 (12%)	1 (4%)
Total no. of noncompliant patients		24	29	26	24
Total Compliant patients		47	42	44	46

DISCUSSION

Base Line Characteristics

In previous studies of the patients of Myocardial infarction in India the mean age of patients were 57.5 years (Xavier et al 2008[10]), 60.4 years (Mohanan et al 2012[11]). 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[10] 56.7% while in study by Mohanan et al[11] 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[10]), 77.4% male and 22.6% females (Mohanan et al 2012[11]).

In study by Mohanan et al[11] 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[10] 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[11] 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.

Compliance During Follow Up

In our study percentage of patients having good compliance for antiplatelet agents was 81% (at 1 month follow up) and 66% (at 6 month follow up). In a study Tuppin et al[12] found 81.7% patients having good adherence for aspirin/clopidogrel therapy during follow up at 6 months after admission for myocardial infarction. In their study Simpson et al[13] found 74% patients having Good adherence for aspirin at 12 month follow up post discharge after treatment for acute myocardial infarction, while Kulkarni et al[14] found 82% patients having good adherence for aspirin at 12 month follow up post discharge after treatment for acute myocardial infarction.

For statins in our study 70% (at 1 month follow up) and 59% (at 6 month follow up) patients were having compliant. Tuppin et al[12] in their study found 76% patients having good compliance for statins, while Simpson et al[13] and Kulkarni et al[14] have reported 84% and 72% patients having good adherence for statins respectively.

For ACE inhibitors or ARBs in our study 80% (at 1 month follow up) and 65% (at 6 month follow up) patients were having good compliance. In their study Tuppin et al[12] found 77.3% patients having good compliance for ACE inhibitors or ARBs while Simpson et al[13] and Kulkarni et al[14] have reported 70% and 72% patients having good adherence For ACE inhibitors or ARBs respectively.

For beta blocker use 77% (at 3 month follow up) and 63% (at 6 month follow up) patients were having good compliance in our study. Tuppin et al[12] found 68% patients having good compliance for beta blockers in their study. Simpson et al[13] and Kulkarni et al[14] found 74% and 78% patients having good adherence for beta blockers during follow up respectively.

Reasons for Non-Compliance

The World Health Organization has categorized potential reasons for medication nonadherence into 5 broad groupings that include patient, condition, therapy, socioeconomic, and health system–related factors.[15]

Reasons for medication nonadherence[15]

In broader terms, these factors can be categorized in patient-related factors, physician-related factors, and health system/team building–related factors[6]. In our study the most common reasons for non-compliance were related to health system, such as inadequacy of health care resources (patients reported noncompliance to therapy because they were getting medicines for short period (7 days every visit) through government resources, they had to come to hospital from distant places and wait for long time to get medicines etc). Lack of proper communication between health care team (Physician, residents, nursing staff etc.) and patients was an important reason for noncompliance. Patients were not aware of their disease characteristics, components of therapy, duration of therapy etc. due to lack of proper communication. A common cultural attitude held by many patients is a preference for herbal remedies[6]. In our study some patients started taking alternative forms of therapy such as Ayurvedic or Homeopathic medicines due to their concern about side effects of prescribed medicine or they did not perceive benefit from the prescribed medicines.

Financial constrains leading to non-adherence to therapy is a well-known reason for non-adherence. Previous research, mostly from the United States, has shown that cost-related non adherence to treatment is widespread, similarly In a Canadian study, 9.6% of patients reported cost-related non adherence.[7] In our study most of the patients were getting medicines through government resources but some patients who were not taking medicines through government resources reported higher cost of few medicines (such as statins and beta blockers) for their reason for noncompliance. Conditions that are asymptomatic and chronic in nature and require long-term therapy have also been associated with non-adherence. Patients most often become non-compliant for chronic diseases like hypertension where they do not have any unpleasant symptoms even without strict compliance to medication regimen. Estimates of medication non adherence illustrates that the non-adherence percentage is greatest when the patients are symptom free[8]. In our study many patients reported being asymptomatic even without medication as their reason for non-compliance to therapy. Therapy related factors such as side effect of medication (Aspirin induced gastritis, hypotensive symptoms such as light headedness, weakness due to beta blockers or ACE inhibitors/ARBs) and complexity of medication regimen lead to noncompliance in some of our patients.

Socioeconomic factors such as poor social support (few patients were dependent on their family members for coming to hospital), low medical literacy among patient and their caregivers were other reasons for noncompliance.

Categories of Nonadherence	Examples
Health system	Poor quality of provider-patient relationship; poor communication; lack of access to healthcare; lack of continuity of care.
Condition	Asymptomatic chronic disease (lack of physical cues); mental health disorders (eg, depression).
Patient	Physical impairments (eg, vision problems or impaired dexterity); cognitive impairment; psychological/behavioral; younger age.
Therapy	Complexity of regimen; side effects.
Socioeconomic	Low literacy; higher medication costs; poor social support.

Determinants of Compliance/ Non-Compliance

In our study we evaluated whether various determinants such as gender of patients, age, residence, educational status, financial status etc. have any relation to therapy compliance/ noncompliance or not. Rates of evidence-based medication use and long-term medication adherence appear to be lower in women[16]. Previous studies have reported more prevalence of medication non adherence among women but in our study there was no statistically significant difference in medication compliance/non-compliance among men and women. Similarly there was no statistically significant difference in compliance/noncompliance among patients of different age groups or residence. In our study we found a statistically significant relation between educational status of patient and drug compliance (p = 0.001). More educated patients were more compliant to prescribed medicines in comparison to less educated or illiterate patients. In their study Davis et al[9] found that the patients having low level of education are likely to be less compliant to prescribed therapy. They also found that low-literacy patients have difficulty understanding basic information regarding medication dosage.[9] Since therapy cost is an important reason determining drug compliance or non-compliance, patients having high family income are more likely to be compliant to prescribed therapy in comparison to those having less family income. In our study also we found that, patients having high family income were more adherent to prescribed therapy in comparison to those having low family income. This association was statistically significant (p = 0.003). 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 partly follow up was done telephonically.

CONCLUSIONS

Over all non-adherence to prescribed secondary prophylaxis therapy was 23% and 37% at 1 month and 6 month respectively. Adherence to prescribed therapy was high during initial follow up period following index hospitalization for cardiac events and declined significantly over time. Health system related (Inadequate health care resources, lack of motivation and proper communication by health care providers), side effects and complexity of regimen and socioeconomic factors were main reasons for therapy noncompliance. Addressing reasons for non-compliance, adherence to therapy can be improved significantly.

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