

Frequency and Predictors of Non-Compliance to Aspirin Therapy in post Myocardial Infarction Patients

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Abstract

Background: Aspirin non-adherence or discontinuation is associated with an almost three-fold increase in risk of major adverse cardiac events. Compliance, commonly known as adherence, has been a major health care issue. Some studies have reported non-adherence rates to aspirin as high as fifty percent. The main objective of this study was to determine the frequency and predictors of non-compliance to aspirin in post myocardial infarction patients.

Methods: This cross sectional study was conducted over a period of 3 months from May 2015 to July 2015 at Civil Hospital, Karachi. All patients visiting Cardiology out-patient department (OPD) with previously diagnosed myocardial infarction were included in the study. Patients who were not prescribed aspirin or those with contraindication to aspirin therapy such as hemophiliacs and peptic ulcer disease patients, and those with memory problems were excluded from the study. A pre-coded questionnaire was presented to the selected sample of 456 patients. Compliance was assessed through self-report. Chi square test was used as the primary statistical test.

Results: Out of 456 patients, 39% (n=178) were non-compliant to aspirin therapy. The most common reported cause for non-compliance was the failure to remember taking the drug reported by 40.7% (n=72) of the people. The second most common cause was the lack of awareness of the importance of the drug and the possible side effects of not taking it 31.4% (n=56).

Conclusion: It can be concluded that non-compliance to aspirin is a major problem present in Pakistan. With the number of cardiovascular deaths increasing around the globe and in Pakistan, it is vital that non-compliance to aspirin should be taken as a serious issue.

Keywords: aspirin, compliance, myocardial infarction, predictors

1. Introduction

Low dose aspirin (acetylsalicylic acid) is commonly prescribed to patients with a history of myocardial

infarction (MI) or occlusive vascular events (e.g. stroke). Several large randomized controlled trials (RCT's) and meta-analyses of RCT's have clearly demonstrated the efficacy of aspirin in reducing the risks of subsequent MI (secondary prevention), causing mortality in patients with MI, peripheral vascular disease and history of stroke (Antithrombotic Trialists' Collaboration, 2002; Baigent et al., 2009; Elwood & Sweetnam, 1979).

Biondi-Zoccai et al. (Biondi-Zoccai et al., 2006) in a meta-analysis of 50,279 patients showed that aspirin non-adherence or discontinuation is associated with an almost three fold increased risk of major adverse cardiac events (recurrence of MI/stroke). Thus, aspirin is a standard treatment in patients for the secondary prevention of cardiovascular outcomes. Clinical guidelines recommend long-term (usually life long) administration in such patients (Smith et al., 2006; Graham et al., 2007). However, several factors such as daily usage and adverse effects pose considerable compliance issues. Studies have reported non-adherence rates as high as fifty percent (Sud et al., 2005).

Compliance, commonly known as adherence, has been a major health care issue for a long time. Non-compliance can decrease the quality of life and hugely increase the cost of medical care (Appel et al., 2003). More importantly, studies have shown that low compliance is the chief reason of many illnesses (Burt et al., 1995). Many studies have focused and reported non-compliance regarding pharmacological treatment of different coronary risk factors. However, few studies have looked on the issue of compliance to aspirin post MI. It is important to understand that non-compliance can nullify the effects of even the most scientific and optimum treatment plan.

To the best of our knowledge, no study has been conducted in Pakistan to determine the frequency of non-adherence to aspirin therapy post MI. Due to the dreaded complications associated with non-compliance, it will be extremely important clinically to find out the trend and predictors of aspirin non-compliance.

2. Methodology

This cross sectional study was conducted over a period of 3 months from May 2015 to July 2015 at Civil Hospital, Karachi. All subjects' information was kept confidential and a written informed consent was obtained from each participant. All ethical responsibilities were met in accordance with Helsinki law. Since our government hospital is located in the center of the city where people come from all over the city, a good representative sample of the entire city was collected and analyzed.

All patients visiting Cardiology Out Patient Department (OPD) with previously diagnosed MI were included in the study. Patients who were not prescribed Aspirin or those with contraindication to Aspirin therapy such as Hemophiliacs and Peptic Ulcer Disease patients, and those with memory problems were excluded from the study. With a P value taken as 0.58 at a power of 80 and confidence interval of 95%, a sample of 375 was calculated. Accounting for non-respondent bias and incomplete questionnaires, the sample size was increased to 456. Non-compliance was defined as non-adherence to Aspirin Therapy for more than 2 days per week.

The data collection was started after completion of the protocol. A pre-coded questionnaire was presented to the selected sample. Informed written consent was taken from each participant and they were assured about confidentiality of their data. The questionnaire was translated in both English and Urdu language. To avoid non-response bias, the questionnaire used was not too long and did not take much time to complete. The Principal investigator explained the nature and purpose of study to all selected participants. Data were collected from randomly selected patients using survey methodology until the sample size was achieved. Confounder was managed through randomized selection of subjects. Confidentiality and anonymity was maintained to obtain as frank answers as possible. The questionnaire comprised of three parts. Part A was designed to measure socio-demographic data including age, gender, and marital status. Part B determined the reasons for non-compliance such as affordability of aspirin, fear of side effects of aspirin, failure to remember to take aspirin, lack of awareness and lack of verbal enforcement or counseling by the doctor. Part C inquired the follow-up time of the patients, the time taken by the patients to arrive at the hospital once the symptoms occurred and the dosage of the prescribed drug.

2.1 Statistical Analysis

After entering data in IBM SPSS v. 16, the statistical analyses were performed in the same. Since all variables were categorical, frequencies and percentages were computed as descriptive measures. To compare the two groups (Compliant and Non-compliant), chi-square test was executed.

The threshold for assessing statistical significant difference was set at 0.05.

3. Results

Out of 456 patients, 61% (n=278) belonged to the compliant group while 39% (n=178) belonged to the non-compliant group (Figure 1). Mean age among the compliance group was 58.6 with male population amongst the group being 67.3% (n=187). For the non-compliant group, average age was 59.9 with male population being 66.3% (n=118) (Tables 1 and 2).

The most common reported cause for non-compliance amongst the 178 reported non-compliant patients was the failure to remember the taking the drug reported by 40.7% (n=72) of the people. The second most common cause was the lack of awareness of the importance of the drug and the possible side effects of not taking it 31.4% (n=56). This was followed by people who could not afford the drug and people who had possible side effects, hence, being non-compliant. (Figure 2)

Table 1. Demographic data, follow up time and time from symptoms for Compliant subjects (n=278)

Variable	
Age (Mean±SD)	58.6±10.1
Gender (%males)	67.3
Marital Status (%married)	94.6
Follow up in months (Mean±SD)	5.9±2.08
Time from symptoms to hospital in hours (Mean±SD)	4.6±1.51

Table 2. Demographic data, follow up time and time from symptoms for Non-compliant subjects (n=178)

Variable	
Age (Mean ±SD)	59.9±12.1
Gender (%males)	66.3
Marital Status (%married)	93.8
Follow up in months (Mean ±SD)	7.5±2.12
Time from symptoms to hospital in hours (Mean ±SD)	6.2±2.10

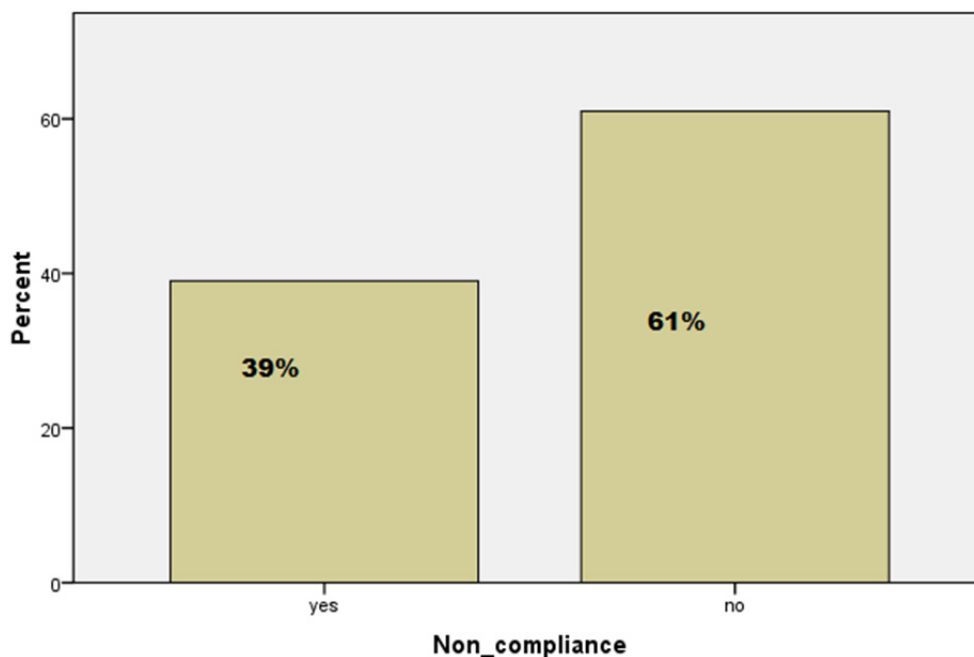


Figure 1. Non compliance of patients taking aspirin (n=456)

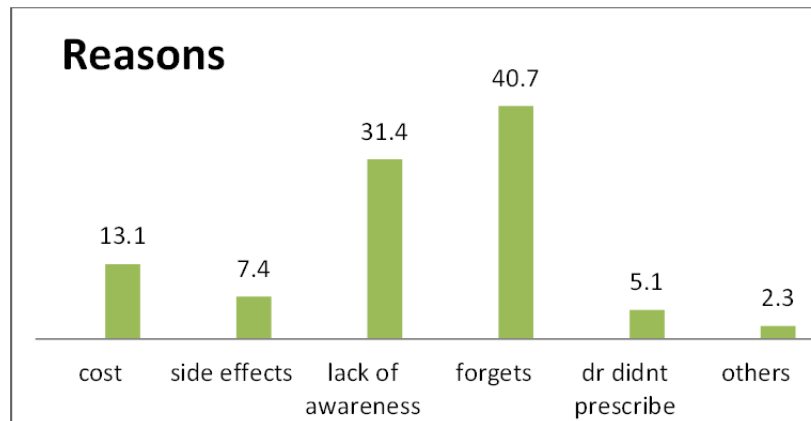


Figure 2. Reasons for non-compliance (n=178)

4. Discussion

Considering the main goal of this study was to determine the frequency of non-compliance to aspirin in MI patients and the most influential factors contributing to it, our main finding was that out of a total of 456 patients an astonishingly high percentage of patients were non-compliant to aspirin therapy (n=178, 39%). This was comparable to the results generated by various other studies that reported discontinuation rates of around 50% (Sud et al., 2005; Appel et al., 2003; Burt et al., 1995; García Rodríguez, Soriano, Martín-Merino, & Johansson, 2009). The prognostic implications of such alarming figures can be multifold. Treatment cessation with aspirin has been shown to be an independent risk factor of an increase in mortality after acute coronary syndrome (Collet et al., 2004). A case control study in UK determined non-compliance to aspirin to be a major predictor of non-fatal MI in patients with a history of ischemic events (Rodríguez, Cea-Soriano, Martín-Merino, & Johansson, 2011), while another study reported the possibility of two vascular events being avoided each day if aspirin were used at a maximum level, with 100% compliance (Morgan, 2012). Other studies indicate premature discontinuation of antiplatelet therapy to be strongly associated with an increased risk of stent thrombosis and death (Rossini et al., 2011). We believe, that the magnitude of the risks involved with non-compliance and the frequency of non-compliance itself, is worrisome and warrants immediate attention.

Our results also indicated that failure to remember taking the drug was the leading cause of non-compliance in patients post MI (n=72, 40.7%). Social factors play a crucial role in determining the patient's compliance to the recommended drug regime with adherence being significantly higher in patients with a greater support system. Having a well-knit friends and family network to serve as a reminder to adhere to the therapy considerably increases compliance. In a study conducted recently, marital status was found to be a determinant of the therapeutic compliance of prescribed drugs with married patient's showing increased compliance to therapy due to help and support from the spouse as compared to their unmarried counterparts (Jin, Sklar, Oh, & Li, 2008). Another study proposed that living alone is associated with a fivefold increase in risk of premature drug discontinuation (Poh et al., 2011). Having friends that follow the same recommended treatment plan further provides help and emotional support leading to an appreciable increment in compliance (Voils, Steffens, Bosworth, & Flint, 2005). Hence, we recommend encouraging family support and establishing phone and letter contacts with the patient. Patients should be provided with paper or electronic diaries to record their daily medication use and the use of telephone follow up should be mandated to ensure regular compliance.

We also found that lack of awareness was the second leading cause of aspirin non-compliance (n=56, 31.4%). Löffler et al. (Löffler, Kilian, Toumi, & Angermeyer, 2003) showed that compliance increases significantly in patients who believe that their illness or its complication could pose severe consequences. We also found a similar trend that patients' knowledge regarding the severity of the disease had a significant effect on compliance. It can be suggested that if patients are explained about the severity of the disease, importance of drugs and potential consequences of non-adherence, then compliance rate increases. This can be achieved easily through extensive counseling by healthcare providers. Therefore, doctors should counsel their patients about the nature and severity of the disease and what treatment plan should be followed (Ponnusankar, Surulivelrajan, Anandamoorthy, & Suresh, 2004). Many previous studies (Haynes, Taylor, Sackett, Gibson, Bernholz, & Mukherjee, 1980; Gonzalez, Williams, Noël, & Lee, 2005; Wild, Engleman, Douglas, & Espie, 2004) have reported that patient's satisfaction with healthcare providers, and belief regarding the treatment is essential for

increased compliance. We also found that lack of belief, amongst patients, regarding antiplatelet therapy as an effective measure to prevent adverse outcomes, is a significant predictor of non-compliance. Another study has also shown that many patients lack understanding of the role that the respective therapies play in their treatment (Ponnusankar, Surulivelrajan, Anandamoorthy, & Suresh, 2004). According to non-compliant patients in our study, counseling sessions by healthcare providers and family members can be the most effective strategy to increase compliance rates. High quality counseling not only provides emotional support and hope to patients but also promotes healthy patient–doctor relationship, which is a strong predictor of compliance.

The cost of medication was also cited as an important cause of non-compliance to aspirin therapy in our study. Although it has been proven that aspirin for secondary prevention of coronary disease is attractive from a cost-effective perspective under a wide range of assumptions (Gaspoz, Coxson, Goldman, Williams, Kuntz, Hunink, & Goldman, 2002), it was identified that a significant proportion of the subjects visiting our health care facilities lived below the poverty line and were unable to resume prolonged anti-platelet therapy due to financial constraints. It has been indicated that with aspirin therapy, the costs of coronary heart disease can decline substantially in the first several years (Gaspoz et al., 2002). Hence, we recommend that the local government should provide such lifesaving treatments at a subsidized rate at each public health care facility so that the overall burden of coronary heart disease can be notably decreased.

Lastly, side effects to aspirin therapy were proven to be a predictor of non-compliance in our study. Although aspirin even in low doses (e.g., 75 mg) can produce minor bleeding (Roderick, Wilkes, & Meade, 1993), it rarely, if ever, causes major bleeding except in patients with an underlying coagulopathy (patients treated with anticoagulants or with hemophiliacs). A small increase in the incidence of stroke in healthy men treated with aspirin was reported in both the American Physicians (Physicians' Health Study Research Group, 1989) and British Doctors (Peto et al., 1988) Primary Prevention Studies (Hennekens et al., 1988) but another study documented aspirin as the cause for reduced incidence of stroke in high-risk patients. The side effects of aspirin are mainly gastrointestinal. Aspirin-induced injury to the gastrointestinal tract can be acute or chronic. Short-term aspirin use produces gastric erosions and gastric hemorrhage, while long-term use can produce gastric ulcers, anemia, and gastrointestinal hemorrhage (Hirsh et al., 1995). This incidence of gastrointestinal effects of aspirin maybe due to geographical variations as well, studies show that there is increased presence of *Helicobacter pylori* in Asian and south Asian communities. This variation including genetic polymorphism could be causing the GIT effects that are causing patients to stop taking aspirin (Gao & Li, 2010).

Thus, the administration of aspirin once daily is recommended for patients with clinical conditions in which antiplatelet prophylaxis has a favorable benefit/risk profile. Because of GI toxicity and its potential impact on compliance, physicians are encouraged to use the lowest dose of aspirin that has been shown to be effective in each clinical setting. Additionally, the physicians should use medication teaching programs to educate patients on the potential benefits of the treatment as opposed to the minor risks involved, to ensure that the effectiveness of the treatment and its vitality is conveyed to the patient.

There are several limitations in our study that need to be considered. Firstly, only patients from a single center were included in our study due to lack of feasibility and finances. Secondly, our hospital is a government based hospital, hence majority of our sample belonged to low socio-economic background. Thirdly, we did not account for all factors that may impact non-adherence such as income, marital status and concomitant psychiatric illness. Lastly, non-compliance was based on patient self-report and not on pill counts, electronic monitoring or refill data, which may be more reliable.

5. Conclusion

It can be concluded that non-compliance to aspirin is a major problem prevalent in Pakistan. With the number of cardiovascular deaths increasing around the globe and in Pakistan, it is vital that non-compliance to aspirin should be taken as a serious issue. There is an urgent need for doctors and nurses to counsel their patients effectively to prevent future morbidities and mortalities because of non-compliance.

Competing Interests Statement

The authors declare that there is no conflict of interests regarding the publication of this paper.

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