

## Assessment of medication adherence in patients at high risk of cardiovascular diseases

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### ABSTRACT

**BACKGROUND:** Adherence to chronic pharmacotherapy is poor. Medication adherence is an important health issue. To better understand its relevance among vulnerable populations requires the availability of a valid, reliable and practical measurement approach. Researchers have proposed various competing methods, including pill counts and self-report measures. Medication adherence has been defined as the extent to which patients take medications as prescribed by their healthcare providers. Poor medication adherence diminishes the health benefits of pharmacotherapy. Elderly patients with coronary risk factors frequently require treatment with multiple medications, placing them at increased risk for nonadherence. **OBJECTIVES:** To test the efficacy of a comprehensive pharmacy care program to improve Medication adherence and its associated effects on blood pressure (BP) and low density lipoprotein cholesterol (LDL-C). **METHODS:** Prospective, Observational cohort study, in this study improvement in medication adherence & its associated effects on the patients before & after pharmacist involvement (intervention) was observed. Pharmacy records are reviewed, medication adherence was measured by proportion of days covered. PDC < 80% was classified as poor adherence. (New York Heart Association) Group A-Hypertension (Usual group), Group B-Hyperlipidemia Intervention group (Pharmacist involvement) After a 2-month run-in phase (measurement of baseline adherence, BP, and LDL-C), patients entered a 6-month intervention phase (standardized medication education, regular follow-up by pharmacists, and medications dispensed in time specific packs). Following the intervention phase, patients were randomized to continued pharmacy care vs usual care for an additional 6 months. **RESULTS:** A total of 200 elderly patients with maximum lying in the age group 60-70 years, taking more than four chronic medications were enrolled. Coronary risk factors included drug-treated hypertension in 102 patients (91.5%) and drug-treated hyperlipidemia in 99 patients (80.6%). Baseline medication adherence was 61.33% in usual care group and 70.44%. After 6 months of intervention, medication adherence increased to 72.22% in usual care and 78.86% in pharmacy care group and was associated with significant improvements in BP and LDL-C. Two months after randomization, the persistence of medication adherence decreased to 69.1% among those patients assigned to usual care, whereas it was sustained at 85.66% in pharmacy care. This was associated with significant reductions in systolic BP in the pharmacy care group vs the usual care group, but no significant between group differences in LDL-C levels or reductions. **Conclusions:** A pharmacy care program led to increases in medication adherence, medication persistence, and clinically meaningful reductions in BP and LDL level whereas discontinuation of the program was associated with decreased medication adherence and persistence.

**Key words:** Hypertension, Medication Adherence, Hyperlipidemia, Pharmacy Intervention

## 1 INTRODUCTION

Adherence has been defined as the “active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce therapeutic results. This definition implies that the patient has a choice and that both patients and the providers mutually establish treatment goals and the medical regimen. Medication adherence usually refers to whether patients take their medications as prescribed as well as they continue to take prescribed medication. Medication adherence is a growing concern to clinicians, healthcare systems, and other stakeholders (eg, payers) because of mounting evidence that non-adherence is prevalent and associated with adverse outcomes and higher costs of care. Medication non-adherence is likely to grow in developing countries as patients take more medications to treat chronic conditions.<sup>1</sup> The rise of performance measures that reward quality based on accomplishment of treatment targets such as blood pressure and low-density lipoprotein (LDL) levels or outcomes such as 1-year mortality after hospitalization for conditions like acute myocardial infarction. Unlike other quality measures that are under more direct control of care providers and healthcare systems (eg, prescribing medications at discharge), the achievement of longer-term therapeutic and outcome goals requires a partnership with patients. Measurement of patient medication adherence use of interventions to improve adherence are rare in routine clinical practice.<sup>2,3</sup> Adults aged more than 50 years of age often have multiple chronic diseases requiring multiple medications. Potential benefits of medications are improved quality of life, preservation of cognitive and physical function, and reduced risk of additional comorbidity and death. Even drugs with well-documented benefits in older adults are not taken as prescribed.<sup>4,5</sup>

“Medication adherence is defined as the extent to which a person’s behavior-taking medication, following a diet, and/or executing lifestyle changes-corresponds with agreed recommendations from a health care provider.”<sup>7</sup> Medication adherence has been a critical topic of discussion among health care professionals and the media in recent years. Taking medication as directed may seem simple, but non-adherence among individuals with chronic conditions is a complex and widespread public health problem. Nearly 3 out of 4 Americans report that they do not always take their medications as directed, which can lead to serious health consequences and significant costs. Many patients fail to fill their prescriptions or pick up their prescriptions or pick up their prescriptions from pharmacy. Others pick up their medications but do not follow their health care professional’s instructions; for example, they might skip doses, stop taking a medication, take more than instructed, or take it at the wrong time of day. Medication non-adherence can influence treatment efficacy by preventing patients from receiving the full benefits of their prescribed medications. It can also cause complications and contribute to conditions

that result in frequent emergency room visits and recurring hospitalizations. According to the New England Healthcare Institute, medication non-adherence costs the US health system an estimated \$290 billion every year, a statistic that is compounded by the fact that chronic diseases affect nearly half of the US population. Of those patients, one third to one half does not take their medications as prescribed.

### Medication taking behavior:

**Compliance** – It is passive following of doctor’s orders.

**Adherence** – The extent to which a person takes medications as prescribed.

**Concordance** – Consultative and consensual partnership between the consumer and their doctor.

**Persistence** – A person’s ability to continue taking medications for the intended course of therapy. **Medication Non Compliance**

In the United States, 50-70% of patients do not properly take their medications. Costs of patient non-compliance are estimated at *over \$100 billion* annually.

### Adherence Vs Non Compliance

Adherence is a more accurate term than compliance. *Compliance* suggests a process in which dutiful patients passively follow the advice of their physicians. *Adherence*, in contrast, better fits how most patients actively participate in their care and decide for themselves when and whether to follow their doctor’s advice.

### Hypothesis

Patient non-adherence with medications can be attributed to 4 key reasons:

- Language Barrier
- Low Education Level
- Poor doctor-patient interaction
- System related obstacles

To begin, how big a problem is poor adherence? It is now established that approximately 60% of patients may not be adhering to long-term treatment regimens 1-2 years later. A good predictor of long-term adherence is adherence at entry into treatment. In other words, adherence behaviour is fairly stable. The distribution of adherence is tri-modal.

## 2 MATERIALS AND METHODS

The present study involves the assessment of medication adherence in patients at high risk of cardiovascular diseases. The patients were recruited from outpatient department (OPD) of cardiac rehabilitation centre and medicine division from Asian Heart Institute and Research Centre, Mumbai, Maharashtra.

### The study involved the following steps:-

#### SITE OF STUDY :-

This study was scheduled conducted in outpatient department of ‘Asian Heart Institute and Research Centre, Mumbai. The protocol was approved by Institutional Human Ethical Committee of R. C. Patel Institute of Pharmaceutical Education and Research, Shirpur.

**STUDY DESIGN:-** Prospective, Observational, Randomized study, in this study improvement in medication

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adherence & its associated effects on the patients before & after pharmacist involvement (intervention) was observed. Pharmacy records are reviewed, medication adherence was measured by proportion of days covered. PDC<80% was classified as poor adherence.(New York Heart Association)

**STUDY SETTING:**

Study was carried out in OPD of medicine division & cardiac rehabilitation centre , who were currently following the check up of hypertension and hyperlipidemia at Asian Heart Institute and Research Centre , Mumbai.

**SOURCE OF DATA:** Collection of all necessary & relevant information from: OPD Card, Laboratory data report, Patient records, Verbal communication with patient

**SELECTION OF PATIENTS:**

All patients were selected based upon the following criteria:

**Inclusion criteria:** 1) Gender (Both male/female)2) Patients who are willing to participate in the study.3) All discharged patients from cardiology department. **Exclusion criteria:** Age below 18 years, Patients who are willing to participate in the study, Inpatients.

**Patients Detail:** The patient detail included Name, Out-patient No., Group, Hospital Name, Consultants Name, Address, Age, Sex, Address, Phone Number, Occupation, Education, Social History, Family History, etc.

**Other Details:** The other details about patient included in proforma were Present Complaints, On Examinations (Blood Pressure, Pulse rate and Weight of patient in each visit of the hospital), Past Medical History, Past Medication History, and Diagnosis.

**3 RESULTS**

In present study, a total of 2000 patients visited to OPD of medicine division at Asian Heart Institute and Research Centre Mumbai. In this study participants were enrolled from August 2011 to Oct 2011, with follow up data collected until April 2012. Approximately 1000 patients visited to the OPD of medicine division, Asian Heart Institute during the study period. A total of 254 patients were screened to enroll in the study. Out of 254 patients, 200 patients were included in the study as per the inclusion and exclusion criteria. Out of those subjects, some were withdrawn from the study due to lost of their follow up and some have serious adverse events. At the end, 190 patients completed the study.

The patient enrollment is shown in Fig. All the patients were randomly attributed assigned to usual care group and intervention group. In present study all enrolled patients were divided into five age groups: from 30-40years, 41-50years, 51-60 years, 61-70 years71-80 years and 81-90 years years shown in the . In this study 10 (5 %) patients were found in the age group of 30-40 years, 34 (17 %) patients were found in the range of 40-50 years, 57 (28 %) were found in the range of 51-60 years, same as 62 (31 %) patients were found in the age group of 61-70 years and 31 (15 %) patients were found in the age group71-80 years and 7(4%) patients were found in age group 81-90 years .

The study revealed that a high percentage of old category among the overall study population. It was believed that, age progresses are more prone to disease and prescription with more drugs . An attempt was made to categorize the overall study population based on the sex (male and female).The study exposed that the overall population of sex categorization study was found to be 115 (57%) males and88(43%) females. An occupation can be used to define socio economic status (SES), the occupation held for the longest period during the working life was recorded .

The study revealed that out of 202 patients prescription 58% (116) patient were business,44% (88) were employed ,19%(38) were housewife , 21%(42) were retired ,3.50% (7) were other professionals. In present study all enrolled patients were divided into two Diet groups: vegetarian patients as well as mixed dietarian patients. Fig shows that categorization of the patients enrolled in the study as per their diet status. In the study total 201 patients were enrolled, out of them 98 (49%) were vegetarians and 103(51.50%) mixed diet. Patients were divided into four BMI groups: Underweight, Normal, Overweight and Obese catagory. 16 (8 %) patients were found in the group of Underweight catagory, maximum patients 69 (34.50 %) were found in the Normal catagory, same as 61 (30.50 %) were found in the Overweight catagory and minimum patients 55 (27.50 %) were found in the Obese category. the patients disease wise distribution is shown were 96%(184) patients are suffering from hypertension 81%(162) patients are suffering from hyperlipidemia 57.5%(115) patients are suffering from more than four health issues. As in the fig below the patients participation in usual care are 34.5%(69) patients suffering from hypertension 30.5%(61) patients suffering from Hyperlipidemia and 19%(38) patients are suffering from more four health issues. In Pharmacy care group 38.5%(77) patients are suffering from hypertension 34.5%(69) patients are suffering from hyperlipidemia and 26% (52) patients were suffering from other health issues .

**Morisky Medication Adherence Scale:-**

Scores for both response versions were skewed with majority of subjects reporting good adherence as shown in the fig. When responses of MMAS was cross referenced with the open the changes in the clinical references , some inconsistencies were observed .Some who scored low on scale reported non adherence for reasons not captured by scale items(Eg.Drug regimen ws modified).

**Table 1.**

Questions	Percent (number)
Responses ( Coding)	0 1 2 3 4
Do you ever forget to take your medications?	48.8 37.5 12 .5 0.6 0. 6
Are you careless at times about taking your medications?	80.0 11.3 8.1 0.6 0.0
When you feel better, do you sometimes stop taking your medications?	83.8 4.4 9.4 1.9 0.6
Sometimes if you feel worse when you take your medications, do you stop taking them?	77.5 6.9 7.5 1.9 6.3

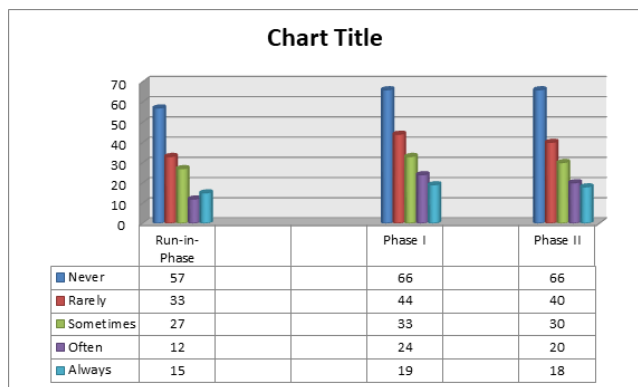


Figure 1.

Of the 200 study patients, 1 did not provide complete baseline assessments; therefore, 199 contributed to the data. The percentage age of the study patients was 60-80 years. Cardiovascular risk factors were prevalent, including drug treated hypertension in 184 patients (91.5%) and drug-treated hyperlipidemia in 162 patients (80.6%). The patients took different chronic daily medications. Baseline medication adherence at completion of run-in phase was 61.2% (13.5%). After initiation of the 6-month pharmacy care program, there was improvement in medication adherence noted at the 4-month pharmacy visit. At 4, 6, and 8 months, medication adherence was 96% or higher. At the conclusion of phase 1 (8 months), the primary end point was met with a medication adherence of 96.9%, representing an absolute change in adherence of 35.5% . The proportion of patients in whom all chronic medications were taken with an adherence rate of at least 80%, a commonly accepted cut point for defining an acceptable level of medication adherence, increased from 5.0% to 98.7%.

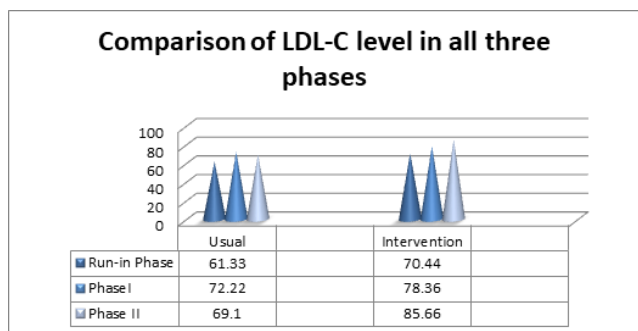


Figure 2.

Improved adherence was associated with improvements in both secondary end points (BP and LDL-C). Among patients with drug-treated hypertension (n=184), systolic BP was reduced . Diastolic BP was not significantly reduced. There was no change in the number of antihypertensive agents taken from baseline to the end of phase 1. Among patients with drug-treated hyperlipidemia (n = 162), LDL-C decreased from (26.1) mg/dL to 86.8 mg/dL.

Following successful completion of phase 1 (n=159), patients were randomized

to either continued pharmacy care (n=83) or were returned to their previous (baseline) method of medication administration (usual care; n=76). The characteristics of the 2 groups were similar with respect to age,sex, baseline medication adherence, and other baseline characteristics.

The continued pharmacy care group showed sustained mean (SD) medication adherence (95.5%)

,whereas medication adherence declined in the usual care group(69.1%).

The run-in phase includes months 1 and 2. Phase 1 is pharmacy care including medications educations for months 4, 6, and 8. Medication adherence may exceed 100% when patients

Mistakenly take more medications than they should (duplicate consumption of medications).

(compared with their baseline method of medication administration)of receiving help with their medications . A prespecified analysis of the associated changes in BP and lipid levels in the continued pharmacy care group showed significant reductions in systolic BP and diastolic BP .The mean (SD) number of antihypertensive agents used was similar between treatment groups (continued pharmacy care vs usual care)

The LDL-C was not further reduced in 9 months in the continued pharmacy care group and was not different between study groups. Patients who did not complete the run-in phase, phase 1, and phase 2 were comparable with those patients who completed each phase with respect to all baseline characteristics as shown in Table 1, except dropouts after phases 1 and 2 were more likely to be men. Among patients who completed the study, compliance with study visits was 100% in that the study was the source of refill medication.

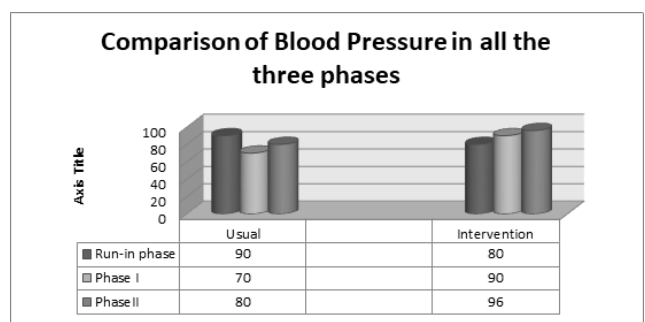


Figure 3.

#### 4 DISCUSSIONS

This study required to investigate the effect of a comprehensive pharmacy care program composed of clinical pharmacist education and use of self assessment technique like Morisky medication adherence scale in the population and to associate this intervention to improved control of BP and

LDL-C, surrogates of clinical risk for cardiovascular. Patients sometimes have difficulty following complicated treatment regimen. In this study patients with drug treated hypertension and drug treated hyperlipidemia were assigned to pharmacist care and usual care. Patients were assessed for their knowledge and provided instructions for their medication use. As per the record, during the 9<sup>th</sup> month intervention, patients in the intervention group had greater medication adherence than patients in usual care group. This difference can be dissipated within 2 months of stopping intervention. Patients in intervention group also had fewer exacerbations resulting in emergency department visits or hospitalizations than patients in usual care group. Pharmacist education intervention can improve medication adherence and outcomes in patients at high risk of cardiovascular diseases.<sup>9</sup> Medication nonadherence among older adults is a prevalent and costly problem. Among adults aged 65 years or older, the prevalence of patients with 2 or more chronic health problems is high (65%)<sup>13</sup> and leads to frequent use of multiple medications. Predictably, the complexity of these regimens promotes medication nonadherence.<sup>4,5</sup>

Medication nonadherence is particularly problematic for asymptomatic conditions, such as hypertension and hyperlipidemia, despite a favorable tolerability profile of many medications used in their treatment. In a retrospective study<sup>16</sup> of 4053 patients aged 65 years or older prescribed medications for hypertension and hyperlipidemia, the adherence to both classes of medication decreased rapidly to 40.5% at the 3-month interval, and then to 32.7% at 6 months and thereafter stabilized.<sup>7,8</sup> Low adherence rates lead to increased adverse health outcomes, including increased ambulatory care visits, emergency department visits, and hospitalizations. In a claims database analysis, patients who were adherent and who had either hypertension or hyperlipidemia showed up to 50% lower all-cause hospitalization risks.<sup>5</sup> This problem may be magnified in the treatment of cardiovascular conditions, in which up to 50% of cardiovascular admissions may be attributable to nonadherence. Furthermore, although drug costs for adherent patients are higher, overall health care costs related to fewer hospital admissions are substantially lower in patients who are adherent. In contrast with the extensive existing literature on the effectiveness of pharmacological interventions, few prospective trials of adherence interventions have been conducted, and evidence from randomized trials is scant.<sup>8</sup> These trials have provided little evidence to date that medication adherence can be consistently and durably improved within the resources typically available in clinical settings, and that such intervention lead to improved health outcomes. In general, multicomponent interventions, including cognitive and behavioral characteristics, are believed to be most effective. Several limitations to the present study are approved. The generalizability of our results is limited to elderly patients taking multiple chronic medications and may not apply to specialized populations, such as elderly individuals in assisted living or those with memory problems. Our study did not evaluate formal measures of cognitive function. Our study design provides evidence on

its global impact on adherence, BP, and LDL-C, but cannot distinguish the individual impact of its components.

## 5 CONCLUSIONS

According to the study we conclude that complete pharmacy programmes composed of patients education and self assessment technique was associated with significant and sustained improvements in medication adherence among patients receiving complex medication adherence with reduced levels of blood pressure and LDL-C suggests that such programmes may lead meaningful improvements in health outcomes. The results of the study are for greater emphasis within healthcare delivery system and different organizations on development and promotion of clinical programmes to enhance medication adherence particularly at high risk elderly population.

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[1–10]

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