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A PROSPECTIVE STUDY OF MEDICATION ADHERENCE AMONG CARDIOVASCULAR PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

The purpose of the study is to evaluate how effectively cardiovascular disease patients take their medications. In Vivekanandha Medical Care Hospital, 155 cardiovascular patients participated in a prospective observational trial that lasted six months. The enrolled patients were assessed for medication adherence using the Manipal Scale for Cardiac Drug Compliance at the baseline, follow-up 1, and follow-up 2 visits. The adherence rate data was evaluated using GraphPad Prism 9. Higher scores on this measure indicated non-adherence. The degree of drug compliance in follow-up 2 was higher than it was in baseline and follow-up 1. Our study found that patients' levels of adherence increased when they received counselling regarding drugs and their use in the management of disease. The study's conclusions indicate that a patient self-report instrument for assessing medication adherence is a potentially useful technique to improve medication adherence and can be used successfully as a tool to guide adherence-based counselling during clinical visits.

KEYWORDS: Drug Compliance, Patient Counselling, Clinical Visit, Self-Report.

INTRODUCTION:

India has one of the highest burdens of cardiovascular disease (CVD) worldwide. The annual number of deaths from CVD in India is projected to rise from 2.26 million (1990) to 4.77 million (2020). Most of the CVD patients are treated with drugs including anti-platelets, cholesterol lowering and anti-hypertensive drugs. For the effectiveness of the treatment, the drugs prescribed should be appropriate and the patients should properly adhere to the

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medications. Medications play a crucial role in managing these conditions, preventing complications, and improving the quality of life for patients. Poor medication adherence can lead to disease progression, increased hospitalizations, and higher mortality rates. However, at some point 50% of the CVD patients stop taking their medications after the commencement of the therapy. The World Health Organization defines Medication Adherence as "The degree of extent to which a person's behavior, corresponds with agreed recommendations from a health care professional"¹. Studies carried out in Saudi Arabia discovered that non-compliance in antihypertensive drugs rates vary between 54 and 72%². Non-adherence to prescribed medications. This can be due to various factors such as forgetfulness, misconceptions about medications, side effects, financial constraints, and lack of understanding about the disease. Non-adherence results in suboptimal outcomes, increased healthcare costs, and reduced efficacy of treatment.

Increased morbidity and death in CHD are both correlated with suboptimal prescribing and poor patient adherence³. Patients who do not take their medication as prescribed lose the benefits of taking statins. According to reports, only 50% of patients who are taking statins after six months and only 30% to 40% after a year still take their prescription. Therefore, it is essential to identify statin non-compliance in order to maximize the clinical benefit of statins⁴.

According to recent predictions, 6.5 million American adults already suffer from heart failure, and by 2030, that number is expected to rise to 8 million^{5.} The study can explore various factors that impact medication adherence, such as socio-demographic factors, patient education, patient-provider communication, medication complexity, and social support. Understanding these factors can help healthcare professionals tailor interventions to improve adherence rates. Although there are many factors at play, common obstacles to adherence are frequently within the patient's power, therefore paying attention to these patient-related issues is a crucial first step in enhancing adherence. Interviewing patients with questionnaires or using patients' self-reports has the advantage of being simple and inexpensive to be carried out.⁶ Patient education is an important component of healthcare. CVD patients often express a lack of knowledge about complications, the importance of adherence, and other lifestyle modification to maintain the disease under control. Patient education aims to improve these limitations after assessing the knowledge, attitude, and practice of individual patients. In summary, the proposed study on medication adherence among cardiovascular patients in a tertiary care hospital is essential due to the widespread implications of poor adherence on patient outcomes, healthcare costs, and the overall management of cardiovascular diseases. It has the potential to provide valuable insights and contribute to improved patient care and outcomes in a critical area of healthcare. Based on the preceding data, a study on improving medication adherence in cardiovascular patients was conducted in a tertiary care hospital.

METHODS AND MATERIALS:

Study Setting: In the Cardiology Department of the 300-bed Vivekananda Medical Care Hospital, Elayampalayam, a six-month prospective observational study was carried out. SVCP/IEC/SEP/2022/05, dated September 17, 2022, is the Institutional Ethical Committee approval number.

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Study population: Cardiology patients who came to take their treatment during the data collection period are included in the study population. About 227 individuals underwent an initial assessment, and following a careful evaluation of specific criteria for inclusion and exclusion, a total of 155 participants were selected to be part of our research project. Once we obtained consent from these patients, we proceeded to gather data using a custom-designed data entry form.

Eligibility Criteria:

The study included individuals receiving medical care on an outpatient basis, encompassing both male and female patients. Additionally, patients under the age of 80 with coexisting medical conditions and the utilization of over 2 medications were considered. On the other hand pregnant women and minors, patients hindered from responding due to mental health conditions during the interview, individuals who declined participation, and those recently diagnosed with cardiovascular disease were not included.

Sample size determination:

The determination of the sample size was based on the single population proportion equation. Taking into account the lack of a comparable study in Ethiopia as recognized by the researchers, the proportion of treatment non-adherence for significant mental illnesses in concurrent cases, along with associated factors, was set at 50%. With a confidence level of 95%, a permissible margin of error of 5%, and an estimated non-response rate of 10%, the resultant sample size was determined to be 155 individuals.

Study tools:

Patient case report, Medication chart, Designed data entry form, Manipal Scale for Cardiac Drug Compliance⁷, Patient counselling pamphlet, Pill box, Pill calendar, Medication reminder application, Patient and patient's caretaker interview.

Manipal Scale for Cardiac Drug Compliance:

This scale comprises 10 questions, were question number 1-6 and 8, 10 have choice of yes=0.5, no=1 whereas question 7 and 9 have choice of yes=-0.5, no=0. The scale's scores were classified as follows: High Drug Compliance (score <1), Medium Drug Compliance (scores between 2 and 3), and low drug compliance (scores >3). The recording of scores was accomplished through in-person interviews with either the patients themselves or their caregivers.

Data collection procedure: The data was initially organized in English, subsequently translated into local language. The data collection process accommodated the preferences of respondents, who could choose either language. The primary data was gathered directly from individual patients. The questions encompassing socio-demographic and economic aspects, clinical considerations, factors related to the healthcare system, as well as factors specific to the patients themselves. Secondary data was collected from the patient chart regarding the medications, frequency and its duration.

Data analysis: The collected data was analysed by using Graph Pad Prism 9 software. The medication adherence levels were assessed using repeated measures one way ANOVA. The P value <0.05 was considered as statistically significant. The adherence level between baseline, follow up 1 and follow up 2 were compared using Turkey's multiple comparison test.

Patient counselling:

The patient counselling was done by providing pill box, pill calendar and patient information

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Leaflet in local language. The patients were suggested with an ideas of pill box and designed pill calendar to improve their level of drug compliance. The patient information leaflet was designed to make patients aware on various aspects of heart diseases, importance of Medication Adherence and counselling were given after assessing patient's adherence to medication.

RESULTS

SOCIO-DEMOGRAPHIC DETAILS:

A total of 155 patients participated in the interview, out of which 47 (30.32%) were females. The age group most frequently affected by cardiovascular conditions was 61-70 years. The highest occurrence of cardiovascular cases among males was observed in the age group of 51-70 years, while among females, it was between 61-70 years. In terms of education, 65 patients (41.93%) were illiterate. Among the entire patient group, the social history indicated that 24 (15.48%) were smokers, 19 (12.25%) were alcohol consumers, 3 (1.93%) used tobacco, and 12 (7.74%) had both smoking and alcohol habits. A significant proportion, 124 patients (80%), had multiple co-existing medical conditions, with 82 (52.9%) of them having hypertension. (Table 1).

DEMOCRAPHIC DETAILS	PERCENTAGE (%)			
DEMOGRAPHIC DETAILS	(n=155)			
Gender				
Male	69.67			
Female	30.32			
Age				
31-40	3.87			
41-50	22.58			
51-60	27.09			
61-70	28.38			
71-80	18.06			
Gender wise distribution among age	MALE	FEMALE		
groups	3 77	4 25		
31-40	22.22	73 A		
41-50	22.22	23.4		
51-60	28.7	27.5		
61-70	16.66	21.05		
71-80	10.00 21.27			
Level of education status				
Illiterate	41.93			
High School	40			
Graduate	18.06			
Pattern of social history				
Smoker	15.48			
Alcoholic	12.25			
Tobocco	1.93			
Both smokers and alcoholic	7.74			

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Patients with co-morbidites	
Patients with 1 co-morbidity	20
Patients with >1 co-morbidities	80
List of comorbidities	
Hypertension	25.15
Ischemic Heart Disease	8.28
Coronary Artery disease	14.11
Myocardial Infarction	23.92
Diabetes Mellitus	23.31
Chronic Kidney Disease	0.92
Pulmonary Disorders	2.45
Lipid disorders	1.84

TABLE 1: DEMOGRAPHIC DETAILS

PRESCRIPTION PATTERN OF MONOTHERAPY, DUAL THERAPY AND TRIPLE THERAPY IN CARDIOVASCULAR DRUGS

Within the study population, various categories of cardiovascular medications were administered as mono therapy, dual therapy, and triple therapy. Notably, nebivolol was the most frequently prescribed medication for mono therapy. Dual therapy primarily involved the prescription of Atorvastatin + Clopidogrel. In the context of triple therapy, the combination of Rosuvastatin + Aspirin + Clopidogrel was the prevailing prescription choice (Table 2), (Figure 1,2,3).

Drugs prescribed	Percentage (%)
MONO THERAPY	
ACE Inhibitors Enalapril Ramipril	2.22 0.87
Anti-anginal	
Digoxin	0.87
Nitroglycerin	1.74
Anti-arrhythmic	
Amiodarone	1.16
Anti-coagulant	
Rivaroxaban	1.45
Anti-platelet	
Aspirin	3.19
Clopidogrel	7.26
Prasugrel	0.87
Ticagrelor	4.36

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ARBs	
Telmisartan	6.39
Valsartan	1.16
Beta Blockers	
Atenolol	1.16
Bisoprolol Fumarate	4.94
Carvedilol	2.9
Nebivolol	11.04
Calcium Channel Blockers	
Amlodipine	2.9
Azelnidipine	2.03
Benidipine HCl	2.32
Cilnidipine	1.74
Diuretics	
Chlorthalidone	0.58
Furosemide	0.87
HMG CO-A Reductase inhibitors	
Atorvastatin	8.72
Pitavastatin	0.58
Rosuvastatin	5.81
Proton pump inhibitors	
Esomeprazole	2.9
Omeprazole	0.58
Pantoprazole	3.19
Rabeprazole	6.97
H2 Receptor Blockers	
Ranitidine	0.58
Anti-Diabetic	
Dapagliflozin	1.74
Human insulin	0.58
Metformin	2.9
Pioglitazone	0.87
Teneligliptin	1.74
Vildagliptin	0.58
DUAL THERAPY	
Atorvastatin + Aspirin	3.02
Atorvastatin + Clopidogrel	9.36
Atorvastatin + Fenofibrate	0.6
Clopidogrel + Aspirin	5.43
Dapagliflozin+ Metformin	0.6

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Eplerenone + Furosemide	0.9
Eplerenone + Torsemide	0.9
Esomeprazole+ Domperidone	7.25
Furosemide + Spironolactone	2.11
Glimepiride + Metformin	8.15
Glipizide + Metformin	0.6
Montelukast + Acebrophylline	2.71
Montelukast + Levocetirizine	0.9
Nebivolol + Amlodipine	0.9
Nebivolol + Telmisartan	6.34
Nebivolol + Valsartan	2.11
Pitavastatin + Aspirin	0.9
Prasugrel + Aspirin	5.43
Rabeprazole + Domperidone	9.96
Ramipril + Metoprolol fumarate	0.6
Rosuvastatin + Aspirin	5.74
Rosuvastatin + Clopidogrel	4.53
Rosuvastatin + Fenofibrate	0.6
Sacubitril + Valsartan	1.51
Sitagliptin + Metformin	4.53
Spironolactone + Torasemide	6.34
Telmisartan + Chlorthalidone	3.62
Telmisartan + Metoprolol fumarate	3.62
Vildagliptin + Metformin	0.6
TRIPLE THERAPY	
Atorvastatin + Aspirin + Clopidogrel	29.09
Metformin + Glimipride + Voglibose	16.39
Rosuvastatin + Aspirin + Clopidogrel	41.81
Telmisartan + Metoprolol succinate + Chlorthalidone	7.27
Telmisartan + Metoprolol succinate + Cilnidipine	5.45

TABLE 2: PRESCRIPTION PATTERN OF MONOTHERAPY, DUAL THERAPY AND TRIPLETHERAPY IN CARDIOVASCULAR DRUGS

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FIGURE 1: PATTERN OF MONOTHERAPY DRUGS

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FIGURE 2: PATTERN OF DUAL THERAPY DRUGS

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FIGURE 3: PATTERN OF TRIPLE THERAPY DRUGS DRUG COMPLIANCE LEVEL:

The drug compliance level was listed on the table 3. In overall comparison, baseline showed 48 (30.96%) patients had high adherence, 79 (50.96%) patients had medium adherence, and 28 (18.06%) patients had low adherence to the drug, follow-up 1 showed improvement with 74 (47.74%) had high drug compliance, 68 (43.87%) had a medium drug compliance and 13 (8.38%) had low drug compliance to the drug regimen. With 119 (76.77%) having high adherence, 32 (20.64%) having medium adherence, and 4 patients (2.58%) having low adherence, follow-up 2 demonstrated a substantial improvement among CVD patients in Comparison to follow-up 1 and baseline. (Table 3)(Figure 4).

DRUG COMPLIANCE LEVEL	PERCENTAGE (%) (n=155)	MEAN ± SD
BASELINE		-
High drug compliance	30.96	0.3958 ± 0.2030
Medium drug compliance	50.96	2.2594 ± 0.5673
Low drug compliance	18.06	3.5892 ± 0.1914
FOLLOW UP 1		
High drug compliance	47.74	-0.0135 ± 0.3853
Medium drug compliance	43.87	1.8014 ± 0.5295
Low drug compliance	8.38	3.5769 ± 0.1804
FOLLOW UP 2		
High drug compliance	76.77	-0.5 ± 0.5266
Medium drug compliance	20.64	1.7031 ± 0.5709
Low drug compliance	2.58	3.625 ± 0.2165

TABLE 3: PERCENTAGE OF DRUG COMPLIANCE LEVEL (N=155)

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FIGURE 4: COMPARISON OF OVERALL DRUG COMPLIANCE RESPONSE TO MSCDC QUESTIONNAIRE

The baseline and the follow up 2 response of the number of patients were listed in the (Table 4 and 5).

		BASELINE - Score Obtained			
Sl.no	Questions	Number of Patients (n=155)		Percentage (%)	
		YES	NO	YES	NO
1.	Do you ever forget to take your medication / Have you ever skipped your medication?	128	27	82.58	17.41
2.	Have you ever stopped your regular medication because you were suffering from any other temporary illness?	98	57	63.22	36.77
3.	Have you ever stopped your medication because you no longer had symptoms and you felt that your disease was under control?	101	54	65.16	34.83
4.	Have you ever stopped your medications because you were worried about side effects?	85	70	54.83	45.16
5.	Have you ever stopped your medications because of any bleeding related side effects?	15	140	9.67	90.32

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6.	Have you ever stopped your medications because you could not afford it?	69	86	44.51	55.48
7.	Do you have someone (something) at home to remind you about your medications?	54	101	34.83	65.16
8.	Have you taken your medication every day in the past one week?	60	95	38.7	61.29
9.	Do you have a fixed time schedule for your medications?	11	144	7.09	92.9
10.	Have you ever stopped your medications because you been advised to do so by a local care giver?	40	115	25.8	74.19

TABLE 4: BASELINE MSCDC QUESTIONNAIRE

		FOLLOW UP 2 - Score Obtained			
Sl.no	Questions	Number of Patients (n=155)		Percentage (%)	
		YES	NO	YES	NO
1.	Do you ever forget to take your medication / Have you ever skipped your medication?	64	91	41.29	58.7
2.	Have you ever stopped your regular medication because you were suffering from any other temporary illness?	60	95	38.7	61.29
3.	Have you ever stopped your medication because you no longer had symptoms and you felt that your disease was under control?	74	81	47.74	52.25
4.	Have you ever stopped your medications because you were worried about side effects?	40	115	25.8	74.19
5.	Have you ever stopped your medications because of any bleeding related side effects?	10	145	6.45	93.54
6.	Have you ever stopped your medications because you could not afford it?	52	103	33.54	66.45
7.	Do you have someone (something) at home to remind you about your medications?	112	43	72.25	27.74
8.	Have you taken your medication every day in the past one week?	108	47	69.67	30.32
9.	Do you have a fixed time schedule for your medications?	91	64	58.7	41.29

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	Have you ever stopped your medications				
10.	because you been advised to do so by a local	12	143	7.74	92.25
	care giver?				

TABLE 5: FOLLOW UP 2 MSCDC QUESTIONNAIRE

DISCUSSION:

Cardiovascular disease (CVD) stands as the primary contributor to both mortality and morbidity within Western nations, and more recently, its impact has extended to developing countries as well⁷. In the present research, a higher prevalence of cardiovascular disease was evident in males (69.67%) compared to females (30.32%). This finding aligns with the outcomes of a study conducted by Surarong Chinwong et al⁸. Based on the age wise distribution the patients with the age group of 61-70 were predominant (28.38%) to the development of cardiovascular disease than other groups which were also observed in the study conducted by Fischer Michael A et al⁹. Out of the 155 patients, 80% had multiple comorbidities, surpassing those with just one. This finding supported with the outcomes of a study conducted by Surarong Chinwong et al⁸. Smoking was present in 15.48% of patients, while 12.25% were identified as alcoholics, underscoring the significant role of smoking as a cardiovascular risk factor. This observation was supported in studies by Hyeonju Lee et al¹⁰. The study encompassed with different class of cardiovascular drug treatments. Notably, Nebivolol emerged as the most prescribed medication, followed by Rabeprazole + Domperidone and Atorvastatin + Clopidogrel.

COMPARISON WITH PREVIOUS EVIDENCE:

The aim of this study was to assess the medication adherence rate among cardiovascular patients. In our study the adherence rate during the follow up 2 was 76.77%. whereas it was high in the study conducted by Javier Mariani et al.,¹¹ (95.8%) and the adherence rate was low in the study conducted by Kamlesh Khunt et al.,¹² (72.3%) and Pallangyo et al.,¹³ (25.3%) The variations in treatment adherence findings can be attributed to several factors such as differences in client demographics, study timelines, and the methodologies employed for evaluating medication adherence. These discrepancies in treatment adherence outcomes arise due to the diverse contextual elements present globally, encompassing factors such as treatment settings, patient backgrounds, and assessment tools utilized.

In this study Manipal Scale for Cardiac Drug Compliance was used. This scale is reliable, validated scale and specific to cardiac patients. This scale provides several insights into the participant's compliance with regard to their medication, frequency and about their medication reminder. In this scale the scores were on the higher side which signified that the medication adherence was poor and there were issues of non-adherence. In addition to the mentioned scale, we incorporated supplementary tools including patient counseling pamphlets, pill boxes, pill calendars, and a medication reminder app. Patients expressed that these resources significantly facilitated their ability to remember and adhere to their medication schedules. In comparison to baseline, where 48 (30.96%) patients had high adherence, 79 (50.96%) patients had medium adherence, and 28 (18.06%) patients had low adherence to the drug, follow-up 1 showed improvement with 74 (47.74%) had high drug

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compliance, 68 (43.87%) had a medium drug compliance and 13 (8.38%) had low drug compliance to the drug regimen. With 119 (76.77%) having high adherence, 32 (20.64%) having medium adherence, and 4 patients (2.58%) having low adherence, follow-up 2 demonstrated a substantial improvement among CVD patients in comparison to follow-up 1. Our findings suggested that Patients' adherence levels were increased when they were counselled about drugs and their role in disease treatment. This indicates that the clinical pharmacist's contribution to the improvement of patient drug compliance was crucial. The pharmacist should evaluate the patient's comprehension, clarifying any questions as necessary and re-evaluating the information until the patient has a complete understanding of it. Many patients found that remainder calls, alarms and pill calendars were helpful, particularly for illiterate. For patients with busy lifestyles, SMS and medication reminder applications proved useful.

STRENGTH:

Data was gathered by trained experts using the local language. The translation of queries was overseen by professionals from the language department, and health-related information was communicated to patients who were not adhering to the treatment after their outcomes were known.

LIMITATION:

Electronic monitoring Devices were not used in this study to because of their expensive costs and potential practical problems. Patient responses regarding their adherence to cardiovascular medications could also be subject to potential bias. Medication adherence with drug class were not monitored in this study for separate tool was mandatory.

CONCLUSION:

The study concluded that the level of medication adherence among CVD patients increased during follow up 2 with the help of self-reported questionnaire and efficient counselling. It demonstrated that the impact of clinical pharmacist services in medication adherence were evident and play a significant role in outpatient services.

CONFLICT OF INTEREST: No conflict of interest

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