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A STUDY OF PHARMACEUTICAL CARE IMPACT ON CARDIOVASCULAR RISK IN DIABETIC AND HYPERTENSIVE PATIENTS

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ABSTRACT:

Background: Coronary heart disease is the most common type of heart disease and is the major cause of death in India and a major cause of death worldwide [1]. It was thought previously to affect initially the higher income countries, but now CHD leads to more death in low- and middle-income countries such as India. Lifestyle modification is the main stay of treatment in preventing coronary heart disease. The intervention by pharmacists through pharmaceutical care program can be useful in reducing coronary heart disease risk factors such as increased blood pressure, high blood glucose, and high lipid levels [2-4].

Objective: To study the impact of pharmaceutical care intervention on general cardiovascular risk and to assess 10-year cardiovascular risk using Framingham scoring method.

Method: Hypertensive and diabetic patients (N = 104) aged >45 years of age were enrolled. Written informed consent was obtained from all the patients enrolled. The pharmacist's intervention included counseling on smoking cessation, alcohol reduction, increased compliance, weight reduction, increased exercise, and dietary changes. The parameters measured were blood pressure (both systolic and diastolic), total cholesterol, LDL cholesterol, HDL cholesterol, blood glucose, and body mass index (BMI). Data were gathered at baseline (first visit); and subsequently at second review and third review.

Result: The pharmaceutical care intervention brought a significant decrease in blood pressure (systolic blood pressure by 8.6% and diastolic blood pressure by 9%), blood glucose (fasting sugars by 14.5% and postprandial sugars by 17.9%), total cholesterol by 12.7%, LDL cholesterol by 13.7%, and HDL cholesterol increased by 12.5%. BMI also showed a significant decrease by 5.2%. The mean 10-year coronary heart disease risk decreased from 44.1% at first visit to 30.8 at last visit with a P value of 0.0001 which is very significant.

Conclusion: The pharmaceutical care intervention proves to be a key in reducing the risk of developing cardiovascular disease in the next 10 years.

INTRODUCTION: Cardiovascular disease may be defined as the disease of the heart and blood vessels. It is also called generally as heart disease. Coronary heart disease or coronary artery disease is the most common type of heart disease.

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It is the leading cause of death in the United States in both men and women [5].Coronary heart disease is the major cause of death in India also. It was thought previously to affect initially the higher income countries, but now CHD leads to more death in low and middle income countries such as India. The rates are disproportionately increasing compared to high-income countries. In high-income countries, effective screening, evaluation, and management strategies for CHD are well established, but these strategies have not been implemented fully in India [1].

Some controllable risk factors for heart disease are hypertension, diabetes mellitus, hyper-cholesterolemia, smoking, obesity, and lifestyle. Uncontrollable risk factors include age, sex, and family history. Lifestyle modifications are the mainstay of therapy to prevent coronary heart disease and to prevent the complications associated with CHD. The measures that are recommended along with relative risk reductions [RRR] in overall mortality given in parentheses include:

- Smoking cessation (51%)[6]
- Mediterranean-style diet (70%)[7]
- Increased oily fish (29%) and fish oil intake (17%)[8]

Lifestyle modifications can best be accomplished through the help of a clinical pharmacist. The intervention by pharmacists through pharmaceutical care program can be useful in reducing coronary heart disease risk factors such as increased blood pressure, high blood glucose, and high lipid levels [2-4].

The concept of pharmaceutical care has been accepted worldwide as an important mission of pharmacy. Pharmaceutical care commands that practitioners not only to give away medications, but also to take more responsibility for improving the quality of patients' outcomes. In this "pharmaceutical care" model, the patient passes over the decision-making authority to the pharmacist. Hidden assumptions in delegating this authority include the opinion that the pharmacist knows best and would be in a better position to make a therapeutic decision in the patient's best medical interests with the aim of improving patient's quality of life (QoL) [9].

There is a need for increased government investment in prevention and early detection through national programs aimed at prevention and control of non-communicable diseases including CVDs [10].

OBJECTIVES: To main objective of the present study was to assess the impact of pharmaceutical care intervention on general cardiovascular risk and to assess 10-year cardiovascular risk using Framingham scoring method.

Another objective is to ensure that the medication is taken correctly and the third objective is to improve the compliance of medications.

METHODOLOGY:

Location: This study was conducted in two tertiary care hospitals in Coimbatore viz., Abishek Hospitals and Seetharam Hospital. Both hospitals are hundred-bedded multispecialty hospitals. The patients were enrolled from the outpatient departments of the two hospitals.

Duration of Study: 10 months

Study Population: Total number of population is one hundred and fifty seven (157). From that, one hundred and two (104) patients were selected & fifty five (53) patients were dropped due to irregular follow up.

Inclusion criteria: The salient patient inclusion criteria at time of enrollment included – patients above age 45, patients diagnosed with diabetes and/or hypertension, patients under drug treatment for diabetes and/or hypertension, patients regularly keeping the appointments at the hospital, and patients having up-to-date results for their routine physical and laboratory tests.

Exclusion criteria: The exclusion criteria are patients with previous history of cerebrovascular accidents or myocardial infarction (registered by a physician in the medical records), patients who fail to keep their regular follow-up appointments, patient who don't have results of routine physical and laboratory tests, patients with diagnosis of dementia or other mental disorder (registered by a psychiatrist in the medical records).

Study Design: This is a prospective study carried out in patients with diabetes and hypertension to study the outcome of pharmaceutical care intervention on cardiovascular risk.

Materials Used: Patient data collection form was used to collect the demographic details of patients, patient history, medication history BMI and laboratory values. Structured questionnaire was used to assess the compliance. The clinical pharmacist gave counseling on lifestyle modification.

Online Framingham general CVD risk prediction Calculator was used to calculate the patient's risk of having a heart attack or dying from a heart attack over the next 10 years [11].

Method: The enrolled patients were appraised about the benefits of pharmaceutical care. All patients are categorized as intervention group. Besides the usual care, they also received pharmaceutical care intervention.

The pharmaceutical care intervention consisted of individual follow-ups, medication review, and educative group activities. The intervention was carried out at a frequency of one visit every three months. This schedule was adopted so as not to disturb the routine activities of the hospital. The interventions were aimed at guaranteeing a high rate of compliance to the pharmacotherapy. Morisky 8-Item Medication Adherence Questionnaire is used to assess the patient's compliance [12]. If a patient is found to be smoker or drinker, the clinical pharmacist explained the health hazards of both smoking and drinking alcohol and gave counseling to help the patient to quit smoking and drinking altogether. If the patient is willing to quit smoking, the clinical pharmacist referred the patient to the physician who in turn helps the patient to quit smoking pharmacologically.

Statistical Analysis: The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta. Using this software range, frequencies, percentages, means, standard deviations, Chi square and 'p' values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's chi square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

RESULTS AND DISCUSSION:

Characteristics of Patients: Total number of population is one hundred and fifty seven (157). From that, one hundred and four (104) patients were selected & fifty three (53) patients were dropped due to irregular follow up and were not included in detailed analysis. .In 104 patients, 74 of them were males (71.2%) and 30 of them were females (28.8%). This can be depicted in the following **Table 1**.

TABLE 1: CHARACTERISTICS OF PATIENTS (N = 104)

Characteristics	Category	Number of patients N = 104	%
Sex	Male	74	71.2
	Female	30	28.8
Age Group	Upto 50 years	6	5.8
	51-60 years	56	53.8
	61-70 years	34	32.7
	Above 70 years	8	7.7
	Mean	60 years	
Occupation	Manual	34	32.7
	Sedentary	70	67.3

In age wise distribution, the total 104 patients were divided into different age groups. The above Table 1 shows the age wise distribution of patients. From the above Table 1, we can infer that the people with age above 50 are more vulnerable to the lifestyle disorder than the people below 50 years of age. From the above Table 1, it can also be inferred that the mean age of patients affected with both diabetes and hypertension is 60 years. According to the world health organization fact sheet, the major risk factor for the patients with heart disease and other chronic diseases is the physical inactivity [13].

In the present study, the patients are divided into two according to their occupational status viz., manual and sedentary. The occupational status of the patients in the study is clearly illustrated in Table 1 above. From the above Table 1, it is clear that 67.3% of patients are physically inactive. It is inferred that the lifestyle disorders and, in particular, the cardiovascular risk factors were associated with the type of lifestyle or occupation and the exercises habits of the population. The family history also plays a major role in development of chronic diseases like diabetes and hypertension in the next generation.

From the following **Table 2**, it can be inferred that the total number of patients with family history of diabetes are 80 which constitutes about 76.9% and the total number of patients with family history of hypertension are 62 which constitutes about 59.6% of total population. From this, it is understood that the family history also plays a major role in developing diseases like diabetes and hypertension.

TABLE 2: FAMILY HISTORY OF ILLNESS

Illness	Family history in							
	Father				Mother			
	Yes		No		Yes		No	
	No.	%	No.	%	No.	%	No.	%
DM	30	28.8	74	71.2	50	48.1	54	51.9
CVS	20	19.2	84	80.8	42	40.4	62	59.6

The patients are again further categorized according to the past history of either diabetes or hypertension and their years of presence which can be illustrated in **Table 3** below.

TABLE 3: PAST HISTORY OF ILLNESS

Past history of illness	HTN		DM	
	No. (N=56)	%	No. (N=70)	%
Presence of Illness				
a) < 1 year	18	17.3	10	9.6
b) > 1 year	38	36.5	60	57.7
Absence of Illness	48	46.2	34	32.7

Lifestyle Modification: The dietary habit, exercise habit, smoking and alcohol consumption greatly influences the development of cardiovascular disease. The following **Table 4** shows the impact of pharmacist intervention on lifestyle.

TABLE 4: LIFESTYLE MODIFICATION

Lifestyle Habits	Category	First Visit		Second Visit		Third Visit	
		No.	%	No.	%	No.	%
Smoking	Non-smoker	18	24.3	22	29.8	42	56.8
	Occasional Smoker	16	21.6	12	16.2	6	8.1
	Light Smoker	28	37.9	34	45.9	26	35.1
	Heavy Smoker	12	16.2	6	8.1	-	0
	P Value			0.0001			
Alcohol	Nil	28	37.9	44	59.5	50	67.6
	Occasionally	32	43.2	20	27.0	18	24.3
	Weekend	10	13.5	8	10.8	6	8.1
	Daily	4	5.4	2	2.7	-	-
	P Value			0.0005			
Dietary Habit	Vegetarian	18	17.3	24	23.1	24	23.1
	Non-Vegetarian						
	a) Weekly Once	32	30.8	32	30.8	38	36.5
	b) 2-3 Times	34	32.7	42	40.3	38	36.5
	c) >Three Times	20	19.2	6	5.8	4	3.8
	P Value			0.3878			
Exercise	No exercise	40	38.5	10	9.6	6	5.8
	Home-based	42	40.4	58	55.8	58	55.8
	Walking	20	19.2	60	57.7	76	73.1
	Heavy	-	-	-	-	-	-
	P Value			0.0001			

Body Mass Index: Body mass index is another major indicator of risk of developing heart disease and other chronic diseases. Dyslipidemia is directly related to BMI. Following **Table 5** shows the changes in mean BMI from baseline along with the standard deviation. The pharmacists found out that lot of patients were in the obese range during their first visit and gave counseling about the importance of weight reduction during all three visits. As a result, the BMI showed a significant decrease by 5.2% with a significant P value of 0.008.

TABLE 5: BMI, VITAL SIGNS AND LABORATORY VALUES

Clinical Parameter	Category	First visit	Second visit	Third visit
BMI	Mean	30.64	29.83	29.04
	SD	3.62	3.7	3.67
	P Value		0.008	
SBP	Mean	135.6	129.4	123.9
	SD	12.0	9.2	5.4
	P Value		0.0001	
DBP	Mean	91.5	87.7	83.2
	SD	9.2	7.9	5.3
	P Value		0.0001	
Total Cholesterol	Mean	228.8	211.7	199.6
	SD	25.3	25.7	26.3
	P Value		0.0001	
HDL	Mean	36.1	38.9	40.6
	SD	7.3	6.5	6.3
	P Value		0.0001	
LDL	Mean	164.4	150.9	141.9
	SD	21.2	18.9	17.6
	P Value		0.0001	
Fasting Glucose	Mean	111.3	101.6	95.2
	SD	8.4	7.9	7.3
	P Value		0.0001	
Postprandial Glucose	Mean	183.1	163.7	150.3
	SD	20.2	17.7	16.1
	P Value		0.0001	

Blood Pressure: Blood pressure is a major risk factor for developing coronary heart disease. There was a significant decrease in the last visit compared to the first visit of both systolic blood pressure and diastolic blood pressure by 8.6% and 9% respectively with a P value of 0.0001 which is very significant. This is as a result of pharmacist intervention. This can be seen in Table 5. The previous studies have also shown the same pattern of decrease [14-15].

Lipid Profile: Another major risk factor of cardiovascular disease is dyslipidemia. The lipid levels play an important role in developing cardiovascular disease. So, the lipid profile was taken thrice during the study see if there are any positive changes. Total cholesterol showed a significant decline after the pharmacist intervention by 12.7%.

LDL cholesterol decreased by 13.7%. The HDL cholesterol is good cholesterol and it has to be present at least in the normal level and not below that. In the study, as a result of pharmacist intervention on dietary changes and exercise modification, the HDL cholesterol increased by 12.5%. This is can be best seen in above **Table 5**.

Blood Sugar: Hyperglycemia increases the risk of developing cardiovascular disease. Hence, the blood sugars have to be controlled. Previous studies have shown the positive impact of pharmaceutical care on blood sugar level [16-18]. The blood sugar level (both fasting and postprandial) before and after pharmacist intervention is shown in the above Table 5.

10-year heart attack risk based on Framingham score: The main outcome of the present study was the 10-year heart attack risk calculated in percentage using the Framingham scoring system. The 10 year heart attack risk in percentage also showed a significant change.

The mean values have been steadily decreasing from 44.1 ± 21.7 to 36.4 ± 20.1 to 30.8 ± 18.0, which has led to the significant P value of 0.0001, which has been very significant statistically. **Table 6** shows Framingham risk percentage during all three visits.

TABLE 6: 10 YEAR HEART ATTACK RISK (IN %) – FRAMINGHAM FINDING

Framingham Value During	10 year heart attack risk	
	Mean	SD
First visit	44.1	21.7
Second visit	36.4	20.1
Third visit	30.8	18.0
Chi square	21.994	
'p'	**0.0001**	
Significance	**Significant**	

Moreover, the 10-year heart attack risk was categorized into three classification viz., low risk (those with risk score of <10%), intermediate risk (those with risk score of 10-20%), and high risk (those with risk score of >20%). Many patients from the high risk range fell into intermediate risk range and low risk range during second and third visits. The P value at 0.0002 is statistically very significant and this shows that the pharmacist's intervention had decreased the heart attack risk over the visits. This is illustrated in the below **Table 7**.

TABLE 7: HEART ATTACK RISK DURING THE THREE VISITS

Heart Attack Risk	Visit					
	First		Second		Third	
	No.	%	No.	%	No.	%
Low	-	-	6	5.8	6	5.9
Intermediate	14	13.5	20	19.2	32	31.4
High	90	86.5	78	75	64	62.7
Chi square	13.55					
'p'	**0.0002**					
Significance	**Significant**					

The previous studies have also shown the same pattern of reduction in risk [19-20].

SUMMARY AND CONCLUSION: The results shows that the 10-month pharmaceutical care program in diabetic and hypertensive patients reduced glycemia, blood pressure levels (both systolic as well as diastolic), and lipid levels to some extent and thereby reduced the 10-year risk for developing heart attack. The pharmacist intervention contributed to improvement in blood sugar, blood pressure, and blood cholesterol levels independently of pharmacotherapeutic changes.

The results also shows that a pharmaceutical care program that consisted of pharmacotherapeutic follow up and education activities organized by pharmacist reduced the cardiovascular risk scores in diabetic and hypertensive patients. From this study, it can be confidently concluded that the pharmaceutical care intervention plays a vital role in decreasing the heart attack risk over a period of 10 years. Further larger studies are warranted to prove the benefits of a pharmacist's intervention in a larger scale.

The observed reduction in cardiovascular risk scores recommends that such a program can lead to meaningful improvements in humanistic outcomes, quality of life, and reduced economic burden to the patients and also to country.

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