



## Intervention of Screening Programme for Hypertension and Lipid Profile on Prescribing Pattern of Antihypertensive and Antihyperlipidemic Agents

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**Abstract:** The aim of the present study is to assess the impact of screening programme for the patients visiting community pharmacies and factors influencing the prescribing pattern of antihypertensive and/ or antihyperlipidemic agents. The study was designed as a prospective cohort study conducted between December 2017 and November 2019. Data were collected from the hypertensive patients visiting regularly in the 5 selected community pharmacies located at 5 Taluks of Erode district, Tamil Nadu, India. The required data were collected either from the patient's record or interview. Data were collected from 946 (75.68%) patients of 1250 patients visited the selected community pharmacies. 49.4% and 50.6% of patients were randomly allotted to the control (group I) and intervention (group II) groups respectively. In this study 50.56% and 46.67% of males were in group I and II respectively. Average SBP was measured as  $151.5 \pm 11.8$  mmHg and  $168.1 \pm 13.6$  mmHg for the patients in group I and II respectively whereas  $92.9 \pm 9.3$  mmHg and  $92.6 \pm 9.5$  mmHg were the DBP readings among the patients in group I and II respectively. Average total cholesterol was measured as  $253.66 \pm 33.67$  mg/dL and  $271.04 \pm 39.91$  mg/dL for the patients in group I and II respectively. The difference in the prevalence is 0.7 and 2.05 for the antihypertensive and antihyperlipidemic agents respectively whereas the incidence was observed as 4.75 and 2.5 for the antihypertensive and antihyperlipidemic agents respectively. The odds ratio of SBP and DBP is 1.12 and 0.99 respectively in the group II. The values of multivariate analysis showed that there is an agreement between intervention and utilization pattern of antihypertensive and antihyperlipidemic agents. It is to conclude that the preliminary screening of blood pressure and lipid profile showed many patients were not visiting regularly for consultations. The screening programme has resulted in good improvement in the utilization pattern of antihypertensive and antihyperlipidemic agents. The age, lipid levels and comorbid conditions were main factors among the individuals which have determined the prescribing pattern of agents.

**Keywords:** Prevalence, Incidence, Antihypertensive Drugs, Antihyperlipidemic Drugs, Pharmacoepidemiology.

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## I. INTRODUCTION

Cardiovascular disease (CVD) is one of major complications and causes of death worldwide and leading reasons in fast developing countries like India.<sup>1</sup> As per WHO, 80% of CVD deaths occur in developing and in under developed countries more when compared with the developed countries. Around 236 lakhs of people may die due to CVDs by 2030 mainly because of heart diseases and strokes. In India still it is neglected by the low and middle income class population, they undergo treatment whenever having major health issues.<sup>2</sup> Hypertension and hyperlipidemia prevalence is higher. It causes greater risk chances for cardiovascular deaths and health related problems. It also poses a huge threat to health and economic.<sup>3</sup> The above said risk issues may be identified at preliminary stages and can be treated effectively.<sup>4</sup> The timely detection and treatment can decrease cardiovascular and cerebrovascular consequences.<sup>5</sup> But still hypertension is under diagnosed and treated at late stages of hypertension.<sup>6</sup> A proper pharmaceutical care plan (PCP) has to be developed in order to decrease the CV risks of hypertension. PCP should address the good diagnostics method and to improve the therapeutic effectiveness.<sup>7</sup> In the present scenario, there are many effective methods available to diagnose the CV risk issues through social programmes. The patients have to be motivated to report the early signs and symptoms of hypertension to their family physician's to start the treatment at the earliest, and to avoid the complications of hypertension and hyperlipidemia. The physician's by utilizing their experience and evidence based medicine will lead to achieve the therapeutic goals.<sup>8,9</sup> The interventions are aimed at the patients and/ or the physicians. The drug utilization reports will always improve the prescribing pattern.<sup>10</sup> The aim of the present study is to assess the impact of screening programme for the patients visiting community pharmacies and to study the factors influencing the prescribing pattern of antihypertensive and/ or antihyperlipidemic agents.

## 2. METHODS

### 2.1 Study Setup

The present study was conducted among the patients and other care takers visiting regularly at the selected 5 community pharmacies which are located in the 5 taluks of Erode district, Tamil Nadu. The present study protocol was approved by the Safe Search Independent Ethics Committee (Ref. No.: PhD/PC-I; 2016).

### 2.2 Study Design

This was a prospective cohort intervention study.

### 2.3 Study Duration and Period

This entire study was conducted from December 2017 to November 2019 for 24 months.

### 2.4 Selection of Study Population

#### 2.4.1 Inclusion Criteria

The inclusion criteria to select the study participants were:

- (i) age between 21 and 60 years;
- (ii) with hypertension for at least 6 months;
- (iii) with diabetes mellitus, CVD, CVS;
- (iv) with the laboratory testing results like blood sugar levels, microalbuminuria and lipid profile<sup>11</sup>
- (v) willing to participate and providing the informed consent by in written and orally;

#### 2.4.2 Exclusion Criteria

The exclusion criterion to select the study participants were

- (i) Pregnant Woman
- (ii) vulnerable groups;

### 2.5 Grouping of Patients

In this study the patients were divided into two groups, Control and Intervention group.

#### 2.6 Control Group

For this group, the screen programme was not done and just observed their prescription of the drugs prescribed This group was designated as control group (group I).

#### 2.7 Intervention Group

During the screening programme for higher blood pressure or elevated blood lipid profiles among the study participants and had recorded on the data collection form not to be prescribed without screening programme for antihypertensive and/ or antihyperlipidemic agents. The patients who were not monitoring the regular blood pressure/ blood sugar levels and other related tests at proper intervals were explained about importance of testing. Such kind of patients were identified and informed to monitor the parameters. Later, the results were provided to the patients and physicians to start the appropriate therapy and these people were designated as intervention groups (group II). The intervention decisions were left to the discrete of the physicians on the selection of antihypertensive and/ or antihyperlipidemic agents.

#### 2.8 Measurements

Apart from the anthropometric parameters like body weight, height as well as blood pressure, microalbuminuria (twice urine samples were collected at an interval of 24 hours), total cholesterol level and fasting serum blood glucose level were measured among the study participants. From all the study participants demographic parameters like family history including cardiovascular diseases, cerebrovascular diseases as well as myocardial infarctions, smoking status, prescribed antihypertensive and antihyperlipidemic agents. Using a standard balance and scale, the body weight and height were measured and body mass index (BMI) was computed as weight (in kilogram) over the square of height (in meters). Blood pressure was measured at two different intervals in the sitting position at the right arm three times to get concurrent values by using a sphygmomanometer. Blood pressure, total cholesterol and glucose levels were measured using a standardized device. The microalbuminuria levels were measured by nephelometry method. The data, like prescribing drugs were

collected before and after the screening intervention programme.

## 2.9 Definitions

Hypertension is defined as the patients have  $\geq 145$  mmHg of systolic blood pressure or  $\geq 90$  mmHg for diastolic blood pressure. Hypercholesterolemia is defined as total cholesterol level is  $\geq 250$  mg/dL or two values of serum troponin I  $> 2.50$   $\mu\text{g/ml}$  had suffered during previous myocardial infarction.<sup>12,13</sup> In the present study, the patients were divided as smokers, who are currently smoking and/or ceased smoking prior to  $\leq 6$  months and the rest of them belonged to nonsmokers. During the data collection if the subject answered "yes" for the family history of cardiovascular disease, cerebrovascular diseases and myocardial infarction for positively then it is the definition for the presence of respective diseases.

## 3. STATISTICAL ANALYSIS

Statistical analysis was carried out using SPSS 11 and CI (Confidence Interval) with Wilson's Score Methods. For the continuous variables, the data are presented in mean with SD and for discrete variables, the data are represented in terms of percentage. Chi-square test was applied for the differences between the proportions. P value  $< 0.05$  was considered as statistically significant. Dichotomous variables were carried out to estimate the odds ratio at 95% confidence interval.

## 4. RESULTS

In the present study initially 1250 participants were selected for the study. Out of 1250, 304 patients were excluded due

to the reason of missing data. Totally eligible 946 patients successfully completed the study. Among them 49.4% were not receiving intervention whereas 50.6% received intervention. They were divided into two groups as control group (group I) and intervention group (group II). Among the 467 (group I) patients, 50.56% were male and 49.44% were female. The average age of this group was observed as  $41.7 \pm 12.5$  years with a mean body mass index of  $26.9 \pm 3.9$   $\text{kg/m}^2$ . The mean of systolic blood pressure and diastolic blood pressure was observed as  $151.5 \pm 11.8$  mmHg and  $92.9 \pm 9.3$  mmHg among the study patients respectively. Mean of total cholesterol level and serum blood glucose was recorded as  $253.66 \pm 33.67$  mg/dL and  $140.54 \pm 22.04$  mg/dL respectively. Mean of microalbuminuria was observed as  $31.9$   $\mu\text{g/ml}$  and its range was found to be in between  $15.9$   $\mu\text{g/ml}$  and  $61.4$   $\mu\text{g/ml}$ . The percentage of patients with a history of smoking, family history of cardiovascular disease, cerebrovascular accident and myocardial infarction was observed as 44.94%, 33.71%, 4.44% and 11.24% respectively. Among the group II (N=479) patients, 46.67% were male and 53.33% were female. The average age of patients in group II was found to be  $40.3 \pm 14.9$  years with a mean body mass index of  $28.1 \pm 5.0$   $\text{kg/m}^2$ . The mean of systolic blood pressure and diastolic blood pressure was measured as  $168.1 \pm 13.6$  mmHg and  $92.6 \pm 9.5$  mmHg respectively. Mean of total cholesterol level and serum blood glucose was measured as  $271.04 \pm 39.91$  mg/dL and  $152.76 \pm 34.89$  mg/dL respectively. Mean of microalbuminuria was measured as  $30.1$   $\mu\text{g/ml}$  and its range was found to be between  $18.1$   $\mu\text{g/ml}$  and  $66.6$   $\mu\text{g/ml}$ . The percentage of patients with a history of smoking, family history of cardiovascular disease, cerebrovascular accident and myocardial infarction was observed as 54.61%, 41.31%, 1.98% and 7.24% respectively. The data are provided in Table 1.

Parameter	Group I N = 467 (49.4)	Group II N = 479 (50.6)
Male (%)	50.56	46.67
Female (%)	49.44	53.33
Age (years)	$41.7 \pm 12.5$	$40.3 \pm 14.9$
SBP (mmHg)	$151.5 \pm 11.8$	$168.1 \pm 13.6^*$
DBP (mmHg)	$92.9 \pm 9.3$	$92.6 \pm 9.5^*$
TC level (mg/dL)	$253.66 \pm 33.67$	$271.04 \pm 39.91^*$
SBG (mg/dL)	$140.54 \pm 22.04$	$152.76 \pm 34.89^*$
BMI ( $\text{kg/m}^2$ )	$26.9 \pm 3.9$	$28.1 \pm 5.0$
Microalbuminuria ( $\mu\text{g/ml}$ )	31.9 (15.9 – 61.4)	30.1* (18.1 – 66.6)
Smoking (%)	44.94	54.61
CVD family history (%)	33.71	41.31
CV accident (%)	4.44	1.98
MI (%)	11.24	7.24

\* P Value is  $> 0.01$  performed by using chi – square test

In the control group, prevalence before and after intervention for antihypertensive drugs were 17.4 and 18.1 respectively and its mean difference is 0.7. Incidence for antihypertensive drugs was 4.75. In the intervention group, prevalence before and after intervention for antihypertensive drugs were 17.85 (range between 16.9 and 18.8) and 18.8 (range between 20.6 and 22.9) respectively and its mean difference is 3.9. Incidence for antihypertensive drugs was 4.875 (range between 4.25 and 5.50). In the control group (CI 95%), prevalence before and after

intervention for antihyperlipidemic drugs were found to be 5.75 and 7.8 respectively. Their difference is 2.05. Incidences of antihyperlipidemic drugs were 2.5. In the intervention group (CI 95%), prevalence before and after intervention for antihyperlipidemic drugs were 6.125 (range between 5.5 and 6.75) and 11.00 (range between 10.25 and 11.75) respectively and their difference was 4.875. Incidence for antihyperlipidemic drugs was 1.8 (range between 2.9 and 4.7). The data are provided in Table 2.

**Table 2: Prevalence and incidence of antihypertensive and antihyperlipidemic drugs prescribed to the intervention and control groups before and after the intervention**

	Control Group (95% CI)	Intervention Group (95% CI)
Antihypertensive Drugs		
Prevalence before intervention	17.4	17.85 (16.9 – 18.8)
Prevalence after intervention	18.1	21.75 (20.6 – 22.9)
Difference	0.7	3.9
Incidence	4.75	4.875 (4.25 – 5.50)
Antihyperlipidemic Drugs		
Prevalence before intervention	5.75	6.125 (5.5 – 6.75)
Prevalence after intervention	7.8	11.00 (10.25 – 11.75)
Difference	2.05	4.875
Incidence	2.5	1.8 (2.9 – 4.7)

Univariate analysis of the control group showed a mean value of 1.52 (range between 0.56 and 2.98) for males and 1.43 (range between 0.66 and 2.25) for females while computing age, results showed a mean value of 1.01 (range between 0.92 and 1.57). The body mass index showed a mean value of 0.96 (range between 0.91 and 1.13) whereas mean value of SBP and DBP were 1.00 (0.95 – 1.05) and 0.97 (range between 0.93 and 1.11) respectively. Univariate and multivariate analysis among control group showed a mean value of total cholesterol level as 1.29 (range between 1.13

and 1.58) and 1.34 (range between 0.98 and 1.67) respectively. Univariate analysis of the control group showed a mean value of SBG, microalbuminuria, smoking, family history of cardiovascular disease, cerebrovascular accident and myocardial infarction as 0.94 (range between 0.66 and 1.10), 1.05 (range between 1.05 and 1.09), 1.47 (range between 0.77 and 2.44), 1.02 (range between 0.70 and 2.03), 0.46 (range between 0.11 and 5.03) and 0.67 (range between 0.35 and 1.34) respectively. The data are provided in Table 3.

**Table 3: Univariate and multivariate analysis relation among variables and utilization of antihypertensive or antihyperlipidemic drugs after the intervention**

Parameter	Odds Ratio (95% Confidence Interval)			
	Control Group		Intervention Group	
	Univariate	Multivariate	Univariate	Multivariate
Male (%)	1.52 (0.56 – 2.98)	-	1.68 (0.61 – 2.67)	-
Female (%)	1.43 (0.66 – 2.25)	-	1.33 (0.79 – 2.91)	-
Age (years)	1.01 (0.92 – 1.57)	-	1.02 (0.93 – 1.41)	-
SBP (mmHg)	1.00 (0.95 – 1.05)	-	1.10 (0.98 – 1.14)	1.12 (0.96 – 1.15)
DBP (mmHg)	0.97 (0.93 – 1.11)	-	1.01 (0.98 – 1.16)	0.99 (0.96 – 1.34)
TC level (mg/dL)	1.29 (1.13 – 1.58)	1.34 (0.98 – 1.67)	0.91 (0.71 – 1.13)	-
SBG (mg/dL)	0.94 (0.66 – 1.10)	-	1.04 (0.86 – 1.07)	-
BMI (kg/m <sup>2</sup> )	0.96 (0.91 – 1.13)	-	1.02 (0.94 – 0.99)	-
Microalbuminuria (µg/ml) (≤ 30)	1.05 (1.05 – 1.09)	-	1.00 (0.99 – 1.03)	-
Smoking (%)	1.47 (0.77 – 2.44)	-	0.74 (0.43 – 1.18)	-
CVD family history (%)	1.02 (0.70 – 2.03)	-	1.41 (0.67 – 2.45)	-
CV accident (%)	0.46 (0.11 – 5.03)	-	5.42 (0.78 – 6.01)	-
MI (%)	0.67 (0.35 – 1.34)	-	1.58 (0.45 – 6.57)	-

Univariate analysis of the intervention group showed a mean value of 1.68 (range between 0.61 and 2.67) for males and 1.33 (range between 0.79 and 2.91) for females while computing age, results showed a mean value of 1.02 (0.93 – 1.41). The body mass index showed a mean value of 1.02 (range between 0.94 and 0.99) whereas mean value of SBP and DBP were 1.10 (range between 0.98 and 1.14) and 1.01 (range between 0.98 and 1.16) respectively. Multivariate analysis of SBP and DBP showed a mean value of 1.12 (range between 0.96 and 1.15) and 0.99 (range between 0.96 and 1.34) respectively. Univariate analysis among the intervention group for total cholesterol level was 0.91 (range between 0.71 and 1.13). Univariate analysis among the intervention group showed a mean value of SBG, microalbuminuria, smoking, family history of cardiovascular disease, cerebrovascular accident and myocardial infarction

as 1.04 (range between 0.86 and 1.07), 1.00 (range between 0.99 and 1.03), 0.74 (range between 0.43 and 1.18), 1.41 (range between 0.67 and 2.45), 5.42 (range between 0.78 and 6.01) and 1.58 (range between 0.45 and 6.57) respectively. The data are provided in Table 3.

## 5. DISCUSSION

It has been observed from the findings of the present study that the screening followed by intervention to subjects and the doctors has led to reduction in the percentage of unattended hypertension and hyperlipidemia when compared with the control group. Findings of this study shows that, at the baseline nearly 50% of patients were not doing regular visit to the physicians and they rarely underwent for laboratory tests. But, the therapeutic

recommendations given were considered for one of the third study subjects with hypertension and hyperlipidemia. This study identified some of the influencing reasons like comorbid conditions, occupational stress and economic status of the patients. There is no significant difference in the prescribing pattern of antihypertensive and antihyperlipidemic agents between the control and intervention groups at the baseline. The microalbuminuria levels were decreased among the intervention group when compared with control group, the levels of shows that the progression of kidney damage was reduced. The results showed about 17% of antihyperlipidemic and 6% antihypertension agents were increased marginally when compared to other Indian reports (1.84% for antihyperlipidemic and 1.10% for antihypertensive). It has been found that there was an increase in the number of new prescriptions instead of refilling of prescriptions following the screening programme in the control group. This study finding shows that many patients received antihypertensive agents in the intervention group when compared with the control group. The results obtained in the study were similar to the previous findings reported by the Collins et al. In that they have also reported the increase of antihyperlipidemic agents followed by the intervention.<sup>14</sup> Shashank R. Joshi et al observed that an intervention led physician for more effective prescribing behavior.<sup>15</sup> The present study evaluated the effectiveness of intervention screening programme. Both the patients and doctors were informed regarding the starting of the treatment to reduce the hypertension and hyperlipidemia as goal of this study. Later, the patients were informed to visit the physician for regular check-ups to avoid clinical risk factors in the individual patient. This study shows few patients have neglected to check their blood pressure and other laboratory parameters. For these patients we have suggested to consult the physician without further delay and physician has prescribed either antihypertension and/ or antihyperlipidemic agents. Based on the laboratory values of blood pressure, total cholesterol levels, microalbuminuria levels there were few changes made in the patient's prescription. The treatment was started by following a criteria based on JNC VII guidelines, which was less flexible when compared with internationally accepted criteria in which the systolic pressure is > 140 mm Hg and diastolic

pressure is > 90 mm Hg). In this view, the percentage of drugs prescribed was not meeting guidelines criteria. For the subjects with CVDs along comorbid conditions like diabetes, smoking or family history of CVD, the treatment has to be initiated immediately. But, few of the above mentioned causes were considered while taking the decision to initiate the treatment among the study subjects. The data obtained are free from error, so that it was able to compare the effects of screening with successive intervention between the prescription pattern among intervention groups and the study reported by Jainaf Nachiya R.A.M et al, 2011.<sup>10</sup> This seems to be a comparable method as the prescription pattern of pre- and the post-interventions are comparable in both studies. The data collected were highly influenced by the patient(s). Hence, the data were collected from the doctors and pharmacies. The present study was aimed to help the patients and the doctors regarding the use of antihypertensive drugs and antihyperlipidemic drug(s) in appropriate time to avoid risks. This is also to create awareness among the patients for visiting the clinics at regular intervals.

## 6. CONCLUSION

Based on the findings of the present study it has been concluded that, conducting a screening programme at community lead to identify the patients in the proper stages of hypertension with appropriate treatment and also avoid cardiovascular complications induced by the hypertension and elevated levels of lipids. The age, food style, comorbid conditions and other risk factors also plays an important role in prescribing drugs to patients by the physicians.

## 7. AUTHORS CONTRIBUTION STATEMENT

Dr. S. Parimalakrishnan framed hypothesis; Mr. Madheswaran. M collected the data and analysed the results with regard to Dr. R. Manivanan provided idea on designing the manuscript. All the authors were involved in preparing this manuscript.

## 8. CONFLICT OF INTEREST

Conflict of interest declared none.

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