



**International Journal of Biology, Pharmacy
and Allied Sciences (IJBPAS)**

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

**PHARMACOEPIDEMOLOGY, EFFICACY AND PRESCRIPTION
PATTERN OF ANTIHYPERTENSIVE TREATMENT: CROSS
SECTION OBSERVATIONAL STUDY**

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Received 24th Dec. 2022; Revised 25th Jan. 2023; Accepted 8th May 2023; Available online 1st March. 2024

<https://doi.org/10.31032/IJBPAS/2024/13.3.6504>

ABSTRACT

Objective: Systemic arterial hypertension is usually asymptomatic, requires long term treatment and the most important risk factors are cardiovascular mortality and morbidity. The aim of this study is to assess the pharmacoepidemiology, efficacy and prescription pattern of systemic hypertension.

Methods: A cross section observational study, conducted among 70 patients in a tertiary teaching hospital located rural parts of India for 6 months. Standard questionnaires were used to measure prevalence and prescription pattern for hypertension among the selected patients.

Results: Among 70 patients, 57.42% were female, majority of the patients were in the age group between 60 and 69 (42.8%), 74.3% has good knowledge about HTN, 21.42% has family history of HTN. 70.58% and 82.35% were smokers and alcoholic respectively. 68.1%, 60.3%, 46.1%, 42.2%, ACE Inhibitors, beta blockers, diuretics, and CCB respectively, mostly prescribed. 51.4% were prescribed with 2 antihypertensive drugs. The mean systolic and diastolic blood pressures were measured before and after treatment 160±6.71/96±2.79 and 145±4.82/92±3.01 mmHg respectively. 65.7% patients can able to attain the goals as per the guidelines during this study.

Conclusion: Based on the above findings, it is to conclude that most of the patients had good knowledge on hypertension. Combined antihypertensive treatment increases the chances for achieving good control on blood pressure. Family history plays a major role in treating and controlling the blood pressure. Good lifestyle practices like quitting smoking and drinking also helps to control higher BP level. The prescription pattern shows that anti-hypertension goals can easily attained with dual therapy.

Keywords: Pharmacoepidemiology, Hypertension, Anti-Hypertensive drugs, Prescription pattern, Treatment pattern

INTRODUCTION

Hypertension (HTN) is the condition during which the force of the blood against the artery walls is simply too high. Usually hypertension is defined as blood pressure (BP) above 140/90 mmHg and is taken into account as severe if the pressure is above 180/120 mmHg [1]. Hypertension is also known as high or raised blood pressure, which is a condition in which the blood vessels have persistently elevated BP of 140/90 mmHg or higher. Blood is carried from the heart to all the parts of the body through blood vessels. Each time the heart beats, it pumps blood into the vessels [2]. High pressure level often has no symptoms. Over time, if untreated it may cause health conditions like renal impairment and cardiovascular diseases like Ischemic Heart Disease (ISH), Myocardial Infarction (MI), and Stroke. It is a vital risk routine Pressure measurement [3]. BP measures include Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) are important in determining a person's cardiovascular risk. Risk of Cardio

Vascular Disease (CVD) doubles for each 20/10 mmHg in BP and a rise of 5mmHg in normal DBP is related to 35-40% increased risk factor for stroke [1]. Risk for Cardiopathy increases 6 folds in hypertensive patients and in risk for CVD increases within the elderly and in people with factor for cardio vascular mortality and morbidity [3]. Usually asymptomatic is discovered on DM or nephropathy and risk is further increased by smoking, obesity and dyslipidemia [4].

Prevalence of hypertension increases with age. About 50% of the people between the age group of 60 and 69 years are likely to have hypertension. Nearly 1.13 billion people worldwide have hypertension. Also, World Health Organization (WHO) reported that almost 1.5 billion people are likely to have hypertension by 2025 [2]. The reduction in DBP achieved by drug treatment reduces 50% risk of CVD [3].

Types of Hypertension [3] (Table 1)

❖ **Primary or essential Hypertension** (90-95%) – There is no identified cause of high blood pressure.

Secondary Hypertension (5-10%) – Some have high BP caused by other diseases or abnormality leading to sodium retention

and/or peripheral vasoconstriction.

Management of Hypertension

The antihypertensive treatment goal is to prevent morbidity and mortality associated with persistently raised BP, lowering it to an acceptable level, with minimum inconvenience to the patient (**Table 2**).

Table 1: Classification of Hypertension under JNC 7 Guidelines [5]

Class	SBP(mmHg)	DBP(mmHg)
Normal BP	<120	<80
Pre-Hypertension	120-139	80-89
Stage 1 Hypertension	140-159	90-99
Stage 2 Hypertension	≥160	≥100

Table 2: Treatment guidelines as per Joint National Committee (JNC 8) [6]

Age	Condition	Bp goal
≥60 years	Without DM, CKD	<150/90 mmHg
18-59 years	Without co-morbidities	<140/90 mmHg
≥60 years	With DM, CKD or Both	< 140/90 mmHg

The first line Treatment includes Thiazide diuretics, CCBs, ACEIs and ARBs whereas second line the dosage of the initial medication should be increased or a second medication should be added thiazide diuretics, CCBs, ACEIs or ARBs (do not combine an ACEIs with ARBs), third line treatment includes β -blockers, α -blockers, α and β blockers, vasodilators, central α -2 adrenergic agonist, direct vasodilators, loop diuretics, aldosterone antagonist, peripherally acting adrenergic antagonist [6]. In this study taken an attempt was made to assess the incidence, efficacy and prescription pattern of systemic hypertension.

MATERIALS AND METHODS

Study design

A hospital based cross section observational study was performed for 6

months, from December 2019 to May 2020, in the Department of Medicine, Rajah Muthiah Medical College and Hospital. It is 1400 bedded multispecialty, tertiary care teaching hospital located in rural parts of Tamil Nadu, India. The study protocol was approved by the Institutional Human Research Ethics Committee institute prior to commencement of the study (Approval Letter No.: IHEC/564/201; 20.12.2019).

Study Participants

Patients admitted in the medicine department of the hospital with the diagnosis of pre-hypertension and stage 1 hypertension, in the age group from 18 to 80 of years. The patient should be prescribed with minimum single antihypertensive agent for greater than 6 months during the study period were

included in the study. The recruitment of the subject was carried out with the help of a physician who has the knowledge of the patient's history and diagnosis.

Designing of data collection form

The data collection form used in this study consist of patients demographic characters including name, gender, age, personal history, systolic and diastolic blood pressure, name of the drugs, prescribed dosage, frequency, route of administration, clinical diagnosis and type of therapy.

Study procedure

Informed consent forms were collected from the patients prior to the study. The patient demographics, Blood Pressure data, anti-hypertensive drug list were captured from patient case sheets and recorded into data collection forms. Personally, visiting the patients with the diagnosis of HTN of outpatient clinic, inpatients of the medicine department and analyzing medication chart to collect data using validated data collection form. Patient prescriptions were collected to study, if any ADRs occurred in the anti-hypertensive drugs prescribed for the management of Hypertension. The collected data was analyzed by using appropriate statistical tool. Knowledge of the hypertension among the patients was measured by using modified WHO standard questionnaires. Anti-hypertensive treatment dynamics were estimated by the hypertension control during the study

period. Hypertension control was estimated as an incidence of target blood pressure achievement among the patients, BP was measured by using sphygmomanometer. The patients were classified into Stages of BP under JNC 8 guidelines. Target BP level (<140 to 150/90 mmHg) was determined by the use of JNC 8 guidelines.

Statistical analysis

The data was collected and entered in the Microsoft Excel software and interpreted by descriptive statistics that was presented to analyse and express the reports as counts and percentages in the form of tables.

RESULTS

Among 70 patients, 11.76%, 26.47%, 35.29% and 26.47% of male patients were belong to age group of 40-49, 50-59, 60-69 and 70-79 respectively while females were 5.12%, 8.33%, 30.55%, 50% and 5.55% were belong to 30-39, 40-49, 50-59, 60-69 and 70-79 respectively. The age wise distribution is found to be statically significant ($P < 0.0001$). Majority of the patients in the age group between 60 and 69 (42.8%). 34 (48.57%) and 36 (51.42%) of males and females were participated in this study. There is no statically significant found to be among the gender ($P > 0.5$). 21.42% of participants have a family history of hypertension and 78.57% has no family history of hypertension. Statistical significant difference was found between patients with family history of hypertension

and without hypertension ($P > 0.0001$). 70.58% and 29.41% of patients were smoker and non-smokers respectively. Statistical significant difference was observed between smokers and non-smokers. ($P = 0.0006$). 82.35% and 17.6% of patients were alcohol consumers and non-alcohol consumers respectively. Statistical significant difference was found among the alcohol consumers and non-alcohol consumers ($P > 0.5$) (**Table 3**).

Status of knowledge

Patients' knowledge about the hypertension was also examined at the baseline period and end of the study (Post-baseline). The knowledge about the disease during baseline period found to be good and poor with 58.5% and 41.4% respectively. The knowledge about hypertension and its risk factors was found to be statistically insignificant ($P = 0.2908$) at the end of the study period. But at the end of the study (post-baseline period) the knowledge was improved to good (74.3%) and decreased in poor (25.7%) of patients. The overall improvement regarding hypertension and its risk factors was improved and found to be statistically significant ($P < 0.0001$) at the end of the study period. The data are represented in **Table 4**.

Drug category wise distribution

The prescribing pattern of anti-hypertensive treatment was observed among the study populations. 68.1%, 60.30%, 46.10%,

42.30%, 17.30% and 5.71%, ACEIs, β -blockers, Diuretics, CCBs, ARBs and α -blockers of the drugs were prescribed respectively. 34.28% of patients were prescribed with β -blockers, 31.42% of patients were prescribed with CCBs, 28.75% of patients were prescribed with diuretics, 20% of patients were prescribed with ARBs, 62.85% of patients were prescribed with ACEIs and 5.71% of patients were prescribed with α -blockers. The data are represented in **Table 5**.

Drug wise distribution

In our study, 28%, 16%, 15%, 9%, 8%, 6%, 3% and 2% of patients were prescribed with amlodipine, metoprolol, enalapril, furosemide, telmisartan, losartan, nifedipine, ramipril as well as prazosin and chlorthalidone respectively. The data are represented in **Table 6**.

Type of therapy prescribed

In our study, 51.4%, 28.57% and 20.10% of the patients were prescribed with dual therapy, multiple therapies and mono therapy respectively. Statically significant difference was found between mono, dual and multiple therapies ($P < 0.0001$). The data are represented in **Table 7**.

Management of blood pressure

The mean SBP/DBP before treatment was $160 \pm 6.71 / 96 \pm 2.79$ mmHg and found to be improved after the treatment ($145 \pm 4.82 / 92 \pm 3.01$ mmHg) i.e. at the end of the study period. The data are represented in **Table 8**.

Incidence of target BP level

Out of 70 patients, 65.7% and 34.29% of the patients can able to achieve their target BP level and not achieved. Statically significant difference was found between goal achieved and not achieved (P < 0.005).

The data are represented in **Table 9**.

Table 3: Demographic data of study population (N = 70)

Characteristics	N (%)		P- Value
	Male	Female	
Age			
30 – 39	0	2 (5.12)	
40 – 49	4 (11.76)	3 (8.33)	
50 – 59	9 (26.47)	11 (30.55)	
60 – 69	12 (35.29)	18 (50.0)	
70 – 79	9 (26.47)	2 (5.55)	< 0.0001
Gender			
Male	34 (48.57)		
Female	36 (51.42)		> 0.5
Family History			
Yes	15 (21.42)		
No	55 (78.57)		< 0.0001
Personal History			
Smoker	24 (70.58)		
Non – smoker	10 (29.41)		0.0006
Alcohol consumer	28 (82.35)		
Non – alcohol consumer	6 (17.6)		< 0.0001

Table 4: Status of knowledge about the hypertension among the study populations

Status of knowledge	N (%)	P – Value
Baseline		
Good	41(58.5)	
Poor	29(41.4)	0.2908
Post – baseline		
Good	52(74.3)	
Poor	18(25.7)	< 0.0001

If P value is < 0.01 then it is considered as statically significant.

Table 5: Distribution of anti-hypertensive drugs under its category

Drug category	No. of patients (%)	Distribution of category-wise (%)
β-blockers	24 (34.28)	60.30
CCBs	22 (31.42)	42.30
Diuretics	20 (28.57)	46.10
ARBs	14 (20.00)	17.30
ACEIs	44 (62.85)	68.10
α-blockers	4 (5.71)	5.71

Table 6: Drug wise distribution of antihypertensive drugs among the study populations

Drugs	Prescribed (%)
Metoprolol	16
Amlodipine	28
Nifedipine	6
Chlorthalidone	2
Telmisartan	9
Enalapril	15
Losartan	8
Furosemide	9
Ramipril	3
Prazosin	3

Table 7: Type of therapies prescribed among the study populations

Therapy type	Patients (%)	P - Value
Mono therapy	20.10	< 0.0001
Dual therapy	51.43	
Multiple therapy (> 2)	28.57	

Table 8: The mean Systolic and Diastolic BP

Blood pressure	Before treatment	After treatment
Systolic blood pressure (140mmHg)	160.0±6.71 mmHg	145.0±4.82 mmHg
Diastolic blood pressure (90mmHg)	96.0 ±2.79mmHg	92.0 ±3.01mmHg

Table 9: Incidence of target BP level

Target BP level (<140/90mmHg)	Patients (%)	P - Value
Achieved	65.71	< 0.005
Not achieved	34.29	

DISCUSSION

In our study, 51.4% of the study participants were female, majority of the study participants were in a age group between 60 and 69 years 30(42.8%), which shows that the patients has stress and sedentary lifestyle as reported by Kontsevaya AV *et al.*, (2015). The present study report and the literature show a similar report. They reported that females were predominant and most likely affected with hypertension than males in age group of 60-69 years [7]. Knowledge on hypertension was assessed by using standard questionnaires among hypertensive patients. 52(74.3%) of patients had good knowledge. Similar results found in study conducted by

Kontsevaya AV *et al.*, (2015) and Kassahun CW *et al.*, (2020) showed that more patients had good knowledge about hypertension [7, 8]. Out of 70 patients only 15 patients had a family history of hypertension. Majority of study participants 55(78.6%) didn't have family history. Rasainge *et al.*, (2015) reported that most of the study population in their study found have family history of hypertension, which is contemporary with the present findings [9].

Personal history was also taken into an account in order to observe the relationship between the lifestyle changes and a favourable effect on treatment of hypertension. In our study none of the women in study population having the habit

of alcohol and smoking, among 34 male participants 24(34.3%) were smokers and 28(40%) were alcoholic. The results were compared with the study conducted by Bruno CM *et al.*, (2018) and Roerecke M *et al.*, (2017), show that the life style changes should accompany the onset of pharmacological treatment [4, 10]. All the patients had been initially prescribed with antihypertensive drugs and continued with their treatment. While analysing the treatment angiotensin converting enzyme inhibitors (ACEIs) 68.1% were the most frequently used, β -blockers 60.3% were somewhat less frequently used.

Drug classes like diuretics, calcium channel blockers (CCBs), angiotensin II receptor blockers (ARBs), medications with central mechanism of actions were prescribed more rarely in 46.1%, 42.3% and 17.3% respectively. Comparing the received data with the results of the PIFAGOR III multicentre study (2008) the incidence rate of ACEIs prescription in our study was lower than that study 68.1% and 98% respectively. According to PIFAGOR III study data diuretics were the next in the prescription incidence rate, according to our data the next were β -blockers. CCB and ARB had fourth & fifth places based on the results of both PIFAGOR study and recommendations of cardiologist in the referral centre [11]. According to the study of Juric *et al.*, (2019) Diuretics were the

first line therapy choice for most hypertensive patients [12]. Like that the recommendations of the Seventh Joint National Committee (JNC7) guidelines as well as guidelines of the World Health Organization (WHO) and the International Society of hypertension from 2003 proved the same results [13]. But in our study diuretics comes under third place of the anti-hypertensive treatment. With reference to Lamers H *et al.*, diuretics are rarely prescribed in monotherapy because of its insufficiency in BP lowering capacity and side effects, suitable in fixed combination in other hand [14]. The mean systolic blood pressure of the total population was $145.0 \pm 4.82\%$ mmHg, while the mean diastolic pressure was $92.0 \pm 3.01\%$ mmHg. When compared with Saju MD *et al.*, no similar results were found. Majority of the population had hypertension for less than 5 years duration [15]. Target BP level gets elevated by the lack of life style changes and poor patient compliance [4]. Our study shows 65.7% of patients achieved target BP level of $<140/90$ mmHg while 34.3% of population did not achieve target BP level.

The following are the limitations of the present study (i) the participants in the study might have answered some questions differently in order to satisfy the enquirer (ii) inadequate sample size (iii) there might have been some over reporting as these observations are based on self-reported

outcomes and (iv) very short duration of the study.

CONCLUSION

Based on the above findings, it is to conclude that most of the patients had good knowledge on hypertension. Combined antihypertensive treatment increases the chances for achieving good control on blood pressure. Family history plays a major role in treating and controlling the blood pressure. Once again this study also confirms the greater incidences of BP among the patients with family background. Good lifestyle practices like quitting smoking and drinking also helps to control higher BP level. The prescription pattern shows that hypertension treatment goals can easily attained with dual therapy.

ACKNOWLEDGEMENT

We express our profound & sincere gratitude to **Dr. R. Umarani**, Professor in General Medicine, Department of Medicine, RMMCH, and **Dr. S. Parimala Krishnan**, Associate Professor, Department of Pharmacy, Annamalai University, Annamalai Nagar, for their valuable guidance and support, constant inspiration, kind co-operation and great intend to us to fulfill our work in a successful manner.

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