



E-ISSN: 2706-9575  
P-ISSN: 2706-9567  
IJARM 2020; 2(2): 228-231  
Received: 14-05-2020  
Accepted: 29-06-2020

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## Drug utilization pattern of antihypertensive drugs at tertiary care teaching hospital

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DOI: <https://doi.org/10.22271/27069567.2020.v2.i2d.72>

### Abstract

**Introduction:** Hypertension represents a major health problem primarily because of its role in contributing to the initiation and progression of major cardiovascular diseases. This cross-sectional observational study aims at analysing the utilization pattern of antihypertensives used for the treatment of hypertension at a tertiary care hospital in perspective of standard treatment guidelines.

**Materials and Methods:** This is a prospective, cross sectional and observational study carried out in the outpatient of Department of General Medicine of NC Medical College and Hospital. All patients with proven hypertension and put on antihypertensive medications were recruited from the Department of Medicine. The total duration of the study was 1 year *i.e.* December 2019 to November 2020.

**Results:** In our study, the mean systolic blood pressure (mean $\pm$ S.D) of the patients was 154.34 $\pm$ 9.43 and the median was 153. Test of proportion showed most of the patients 53 (44.1%) were significantly higher systolic blood pressure ranging from 160-179 mmHg. The mean diastolic blood pressure (mean $\pm$ S.D) of the patients was 98.32 $\pm$ 8.43. Test of proportion showed most of the patients 51 (42.5%) were significantly higher diastolic blood pressure ranging from 100-119 mmHg. Test of proportion showed most of the patients 62 (51.6%) were on Mono therapy significantly higher than dual therapy, triple therapy and poly therapy, 34 (26.6%), 13 (10.8%), 11 (9.1%) respectively. Causality assessment of ADRs was done using WHOUMC scale which categorizes ADRs as "certain", "probable", "possible" and "unlikely". Table 8 shows that type of reactions and their percentage are as certain (9.6%), Probable/ Likely (67.7%), Possible (19.3%), and Unlikely (3.2%).

**Conclusions:** In this study usage of anti-hypertensive drugs were prescribed rationally in tertiary care hospital. The study emphasizes that need for effective continuing medical education and also preventive measures in hypertensive individuals.

**Keywords:** Anti-hypertensives, angiotensin receptor blockers, drug utilization study

### Introduction

Hypertension is an asymptomatic disorder and usually comes into picture only when the patient presents with some end organ damage, hence it is referred to as a silent killer<sup>[1]</sup>. It is the 3<sup>rd</sup> killer disease<sup>[2]</sup>. World Health Statistics 2012 states that, every 1 in 3 adults has a high BP<sup>[3]</sup>. In 2000 it was estimated that 1 billion *i.e.* nearly a quarter of the world's population is suffering from hypertension. Prevalence of hypertension was estimated to be 40% in adults more than 25years in 2008. It is estimated to increase to 1.56 billion by 2025<sup>[4]</sup>.

India is the second largest country in the world on the basis of its population, so a major chunk of any disease statistics can easily be attributed to her. Hypertension is the most common chronic health disorder in India<sup>[4]</sup>. According to the global status report 2010 by WHO; prevalence of hypertension is 32.5%. Males have a slightly higher prevalence in comparison to females. Recent studies show that for every known person with hypertension, there are two people with either undiagnosed hypertension or prehypertension<sup>[5]</sup>. Three serial epidemiological studies in the years 1994, 2001 and 2003 showed a prevalence of hypertension as 30%, 36% and 51% respectively in males while in females it was 34%, 38% and 51% respectively<sup>[6]</sup>.

Reducing blood pressure with life style modification and antihypertensive drugs can effectively tackle the burden of this disease on our state and the nation. Evidence from several randomized controlled trials has shown that antihypertensive drugs can effectively reduce morbidity and mortality due to hypertension<sup>[7]</sup>.

Hypertension pharmacotherapy and guidelines: Antihypertensive drugs are prescribed mainly to reduce the morbidity and mortality caused by hypertension and its complications. Many a time, patients require more than one drug for effective control of hypertension. Various classes of antihypertensive drugs like diuretics, inhibitors of the renin-angiotensin system, calcium channel blockers (CCB) and beta blockers (BB) have been shown to reduce complications of hypertension and may be used for initial drug therapy [7]. Since the need to improve the control of hypertension is well acknowledged, several guidelines on its classification and management have been developed. Some of the bodies which have developed guidelines are American Society of Hypertension/ International Society of hypertension (ASH/ISH), Joint National Committee (JNC) on Detection, Evaluation, and Treatment of High Blood Pressure, European Society of Hypertension (ESH)/European Society of Cardiology (ESC), National Institute for Health and Care Excellence (NICE) and Japanese Society of Hypertension. The JNC 8 guidelines published in 2014 are the most recent guidelines for the management of hypertension in different clinical settings. These guidelines were developed based on a systematic review of literature to help clinicians, especially the primary care physicians [8]. Despite these guidelines, and also evidence showing that hypertension is a major public health concern, many clinicians fail to assess BP routinely, and in those with a diagnosis of hypertension, do not start treatment or titrate the dosage of the drugs effectively [9]. The available guidelines recommend different goal BP levels and drug treatment options according to patients' individual clinical need.

**Materials and Methods**

The study was conducted at the Department of Medicine in collaboration with the Department of NC Medical College and Hospital. All patients with proven hypertension and put on antihypertensive medications were recruited from the Department of Medicine. The total duration of the study was 1 year *i.e.* December 2019 to November 2020.

**Inclusion criteria**

- Patients of hypertension (diagnosed according to JNC8 criteria; systolic blood pressure >140 mmHg, diastolic pressure > 90 mmHg).
- Patients of either sex of age 18 to 60 years.
- Patients having no associated comorbidities.

**Exclusion criteria**

- Patients unwilling to participate and did not give consent to the study.
- Patients are unable to give an interview.
- Pregnancy/breastfeeding.
- Patients with incomplete medical records.
- Patients with chronic liver disease such as cirrhosis, chronic hepatitis, cigarette, drug addiction, alcohol, acute viral hepatitis.
- Terminally ill or comatose patients.
- Patients with concurrent major psychiatric illness and/or concurrent major medical illnesses.
- Patients already on treatment from some other institution for other indications.
- Patients taking alternate medicines along with the prescribed one'.

The diagnosis of hypertension was confirmed prior to enrolment. Patients were allotted a unique patient identification number for ease of follow up. On the first visit, a case record form (CRF) designed as per the study protocol was filled according to the prescription of the patient (which includes patient demographic details, treatment charts, and investigation reports of patients of medicine). Charting of blood pressure was also done on the first visit. The patient medication chart was recorded every follow-up visit and at 3 months for keeping a record of prescriptions and improvement in terms of clinical parameters. If any serious interaction was observed, health care professional for necessary modifications was informed.

**Results**

In this study total 120 patients were included.

**Table 1:** Distribution of age group

Age group in years	18-40	41-60	61-80
No. of patients	11	77	32
Percent	9.16	64.1	26.6

The mean age (mean±S.D) of the patients was 53.42±8.68 years with range 18-80 years and the median age was 57 years (Table 1). Test of proportion showed most of the patients were significantly higher in the age group 41-60 years.

**Table 2:** Gender distribution of patient

Gender	Male	Female
No. of patients	93	27
Percent	77.5	22.5

The gender ratio of the patient's male: female was found to be 1.2:1. Out of the 120 studied patients, 77.5% (93) of patients were male and 22.5% (27) of patients were female. Test of proportion showed that the male patients were slightly more than the female patients (Table 2).

**Table 3:** Duration of hypertension

Duration in years	< 3 years	4-6 years	> 7 years
No. of patients	73	38	9
Percent	60.8	31.6	7.5

In table 3, test of proportion showed 55 (61.1%) patients were less than 3 years, followed by 28 (31.1%) patients were between 4-6 years and least were 7 (7.8%) were having history of >7 years (Table 3).

**Table 4:** Systolic blood pressure distribution in patients

Systolic blood pressure (mmHg)	120-139 (Pre HTN)	140-159 (Stage 1 HTN)	160-179 (Stage 2 HTN)	>180 (HTN emergency)
No. of patients	9	47	53	11
Percent	7.5	39.1	44.1	9.1

The mean systolic blood pressure (mean±S.D) of the patients was 154.34±9.43 and the median was 153. Test of proportion showed most of the patients 53 (44.1%) were significantly higher systolic blood pressure ranging from 160-179 mmHg (Table 4).

**Table 5:** Distribution of diastolic blood pressure in patients

Diastolic blood pressure (mmHg)	80-89 (Pre HTN)	90-99 (Stage 1 HTN)	100-119 (Stage 2 HTN)	>120 (HTN emergency)
No. of patients	11	49	51	9
Percent	9.1	40.8	42.5	7.5

The mean diastolic blood pressure (mean±S.D) of the patients was 98.32±8.43. Test of proportion showed most of the patients 51 (42.5%) were significantly higher diastolic blood pressure ranging from 100-119 mmHg (Table 5).

**Table 6:** Distribution of drug therapy in patients

Drug therapy	Monotherapy	Dual therapy	Triple therapy	Poly therapy
No. of patients	62	34	13	11
Percent	51.6	26.6	10.8	9.1

Test of proportion showed most of the patients 62 (51.6%) were on Mono therapy significantly higher than dual therapy, triple therapy and poly therapy, 34 (26.6%), 13 (10.8%), 11 (9.1%) respectively (Table 6).

**Table 7:** Utilization pattern of different antihypertensive drugs

Treatment	No. of patients use antihypertensive drug	Percent
<b>Mono therapy</b>		
Calcium channel blocker	23	19.1
ARB	11	9.16
ACE Inhibitor	9	7.5
Beta Blocker	13	10.8
Alpha Blocker	3	2.5
Diuretics	3	2.5
<b>Dual therapy</b>		
CCB+ARB	17	14.1
CCB+Beta Blocker	9	7.5
CCB+ Diuretic	3	2.5
ARB+ Diuretic	3	2.5
Others	2	1.6
<b>Triple therapy</b>		
CCB+ARB+Diuretic	6	5.0
CCB+B Blocker+Diuretic	4	3.3
Others	3	2.5
Polytherapy	11	9.16

Calcium channel blocker was the frequently used class of drug for monotherapy (20%). In dual drug therapies were CCB+ARB accounting for 14.1%, and 5.0% of patients were on triple drug therapy with CCB+ARB+Diuretic. Polytherapy was seen in 9.1% patients

Causality assessment of ADRs was done using WHOUMC scale which categorizes ADRs as “certain”, “probable”, “possible” and “unlikely”. Table 8 shows that type of reactions and their percentage are as certain (9.6%), Probable/ Likely (67.7%), Possible (19.3%), and Unlikely (3.2%).

**Table 8:** WHO causality assessment of ADRs

Type of reaction	No. of patients reported ADR (31)	Percent
Certain	3	9.6
Probable/likely	21	67.7
Possible	6	19.3
Unlikely	1	3.2
Conditional/unclassified	-	-
Unassessable/unclassifiable	-	-

**Table 9:** Severity of reported ADRs by modified Hartwig and Siegel scale

Type of reaction	No. of patients reported ADR (31)	Percent
Lethal	-	-
Severe	1	3.22
Moderate	11	35.4
Mild	19	61.2

**Table 10:** Common ADR reported

Class of drugs	Adverse events experienced	No. of patients	%
CCB	Pedal edema, giddiness, headache, abdominal pain, bradycardia	13	41.9
ARB	Anxiety, Nausea and Vomiting, Headache, Abdominal pain, Restlessness, Itching and inflammatory swelling	6	19.3
ACE Inhibitor	Dry cough, dizziness, headache, drowsiness, diarrhea, hypotension, weakness, cough, rash, metallic or salty taste.	7	22.5
Beta Blocker	Constipation, nausea and vomiting, headache, hypoglycemia, postural hypotension	4	12.9
Diuretics	Hypotension, muscle cramps, headache vertigo, pain in legs, dysuria	2	6.4
Other	Skin reaction	3	9.6

Total 23 patients were reported ADR. 41.9% patients were on Calcium channel blocker inhibitors. 19.3% patients receiving ARB reported side effect.

**Discussion**

The WHO defines drug utilization studies as “the marketing, distribution, prescription and the use of drugs in a society,

with special emphasis on the resulting medical, social and economic consequences.” Prescription pattern surveys are an important methodological instrument of drug utilization studies, which help provide an in-depth insight into the disease profile of patients and prescribing behaviour of clinicians. Hypertension is a very common medical condition worldwide and is the principal cause of stroke, is a

major risk factor for coronary artery disease and its complications. It is a major contributor to cardiac failure, renal insufficiency, and dissecting aortic aneurysm<sup>[10, 11]</sup>. Choice of an antihypertensive drug should be driven by likely benefit in an individual patient, taking into account concomitant diseases such as diabetes mellitus, problematic adverse effects of specific drugs, and cost<sup>[12]</sup>. The overall goal of treating hypertension is to reduce hypertension associated morbidity and mortality.

In this study, the maximum number of patients, were from the age group of 41-60 (64.1%) years followed by 61-80 (26.6%) and least number in 18-40 (9.16%) years of age of patients are from this age group Whereas, total 120 patients were there, including 93 (77.5) males and 27 (22.5) females (Table 2) and showing a predominance of male population. The hypothetical cause of higher number of male patients is elevated levels of androgen such as testosterone as they play a role in elevation of blood pressure<sup>[13]</sup>. A similar study was also conducted by Chobanian AV *et al*, which is supporting this study<sup>[14]</sup>.

Furthermore, maximum number of patients was seen in less than 3 years duration of hypertension followed by 4-6 years of duration and minimum number of patients was seen in more than 7 years of duration. In addition, systolic blood pressure, maximum number of patients in stage 2, followed by stage 1 and hypertensive emergency and lowest number in pre-stage hypertension.

On the other hand, diastolic blood pressure, maximum number of patients in stage 2 followed by stage 1 and hypertensive emergency and lowest number in pre-stage hypertension. In this study, maximum number of patients were on Single drug therapy (51.6%), followed by 26.6% of patients on dual drug therapies, and 10.8% of patients were on triple drug therapy for treatment of hypertension. Calcium channel blocker was the frequently used drug for monotherapy (19.3%), and the most commonly used drugs in dual drug therapies were CCB+ARB accounting for 14.1%, and 10.8% of patients were on triple drug therapy with CCB+ARB+Diuretic. In a study by Shah J *et al*, the most commonly prescribed antihypertensive among elderly patients was Amlodipine<sup>[15]</sup>. This is also in consonance with the recommendations of the JNC on Prevention, Detection, Evaluation, and Treatment of high blood pressure guidelines which state that low dose of different classes of antihypertensive drugs is more beneficial than a high dose of one.

According to WHO-UMC Scale maximum number of ADRs in probable class followed by possible, unlikely and certain class. Moreover, as per the modified Hartwig and Siegel's scale maximum number of ADRs was mild category and lowest in sever type of reaction was observed in this study. No ADRs were found in lethal type of reaction. These findings were consistent with the literature reported by Almas A *et al*, Total 31 patients were reported ADR<sup>[16]</sup>. In our study 41.9% patients were on Calcium channel blocker inhibitors. 19.3% patients receiving ARB reported side effect.

### Conclusion

The knowledge and prescription of drug was concluding to be the base line idea of ADRs of antihypertensive drugs in hypertensive patients visiting OPD of tertiary teaching care hospital in India. In this study, Authors can't say that all of the prescriptions found were rational; furthermore, more changes are needed to be done in prescription of

antihypertensive drugs are needed in drug prescribing practices in hypertensive patients. Patients are needed to provide information and proper counselling regarding the ADRs of drugs; this would refine the quality of life. However, since this study is mainly limited to pattern of drug usage in hypertensive population in a tertiary care hospital, care must be exercised in generalizing the study results to prescribing pattern of the whole region.

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