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# DRUG UTILIZATION STUDY OF ANTIHYPERTENSIVE DRUGS IN A TERTIARY CARE HOSPITAL OF WESTERN MAHARASHTRA- A PROSPECTIVE CROSS-SECTIONAL STUDY

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Drug utilization, antihypertensive drugs, rationale combinations.

#### **ABSTRACT**

**Background:** Hypertension is a major factor causing increasing international burden of morbidity and mortality. Hypertension is associated with various co-morbidities like Coronary artery diseases, Peripheral vascular diseases, chronic kidney diseases, heart failure, atrial fibrillation, eye blood vessel damage, etc. The prescription of antihypertensive drugs varies according to the cardiovascular morbidity, age, overall health status and many other variables. An understanding of the pattern of the drug usage will help to know the rationale behind the prescription of antihypertensive drugs and their combinations and factors considered by the health provider while recommending the drugs. This is a drug utilization study in hypertensive patients in a tertiary care hospital intended to understand the pattern of anti-hypertensive drug usage in a tertiary health- care institution.

**Methods:** Hospital based, prospective observational study, conducted in Medicine OPD from 1<sup>st</sup> September 2019 to 30 November 2019. Study included 316 patients selected through simple random sampling technique.

**Results:** The mean age of participants was  $52.35 \pm 12.56$  years. Out of total 316 patients 173 were males (55%). We observed that Calcium channel blockers were the most commonly used drugs (44%) followed by ARBs (39%) and Beta blockers (32%). Single drugs were used by majority of the patients (78%) followed by 2 drug combinations (15%) and 3 drug combinations in 6% patients. The utilization of generic drugs in our patients was less compared to branded medicines.

**Conclusion:** We conclude that there is a need for finding out the loopholes for the possible low compliance in antihypertensive treatment and necessary actions should be taken to prevent the possible complications by ensuring prompt and adequate treatment of hypertension.

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# **INTRODUCTION**

According to the latest ACA/ AHA guidelines(2017), hypertension can be defined as a systolic BP/diastolic BP  $\geq$  130/80 mm Hg. This silent killer, is a major factor causing increasing international burden of morbidity and mortality. According to a study conducted by PLOS ( Public Library Of Science) in May 2019, among the people with hypertension, only 44.7% people were aware of their diagnosis, 13.3% were treated, and 7.9% had achieved control. Hypertension is associated with various co-morbidities like Coronary artery diseases, Peripheral vascular diseases, Chronic kidney diseases, heart failure, atrial fibrillation, eye blood vessel damage, etc. A therapeutic decision approach based on predicted CV risk is more effective in terms of preventing cardiovascular events.

It is therefore necessary to assess the present drug utilization in hypertensive cases and analyze it to bring out the effective techniques of management with rational usage and combinations of variety of drugs available and apply it appropriately over the masses to attain control over hypertension. A systematic drug utilization study can play a key role in this process.

The prescription of drug varies according to the cardiovascular morbidity and so do the effects and outcome of the treatment. An understanding of the pattern of the drug usage will help to know the factors considered by the health provider while recommending the drugs, as elements like age, overall health status, family history<sup>7</sup>, economic status and associated comorbidities are also taken into account while prescribing the drug. This can be useful while designing plans for effective treatment of hypertension.

This drug utilization study in hypertensive patients in a tertiary care hospital is intended to understand the pattern of antihypertensive drug usage and will be helpful to plan for the

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provision of health services and medications in hypertensive patients.

#### Aims and Objectives

- 1. To evaluate the pattern of prescription of antihypertensive drugs in the hospital.
- To assess the combinations and rationale behind the prescribed drugs.
- To understand the way of implementation of standard guidelines in the prescription of anti-hypertensive drugs by the physicians.
- 4. To analyze the indicators of usage of drugs in different cases.

#### MATERIALS AND METHODOLOGY

- 1. **Study design:** Hospital based, prospective cross-sectional observational study.
- 2. **Study setting:** Study was conducted in Medicine OPD after the approval from IEC.
- 3. **Study duration:** 3 months. (From 1<sup>st</sup> September 2019 to 30 November 2019).
- 4. *Sample size:* n=196.

[178 (with 95% confidence interval) + 18 (for attrition of the cases) =196]

The reference for prevalence of hypertension (13.3%) according to study by Prenissl J *et al*  $^3$  -

# Sample Size for Frequency in a Population

Population size (for finite population correction factor or fpc)(N): 1000000

Hypothesized % frequency of outcome factor in the population (p):13.3%+/-5

Confidence limits as % of 100(absolute +/- %) (*d*): 5% Design effect (for cluster surveys-*DEFF*): 1

#### Equation for sample size

# $n = [\text{DEFF*Np}(1-p)] / [(d^2/Z^21-a/2*(N-1)+p*(1-p)]$

Results from OpenEpi, Version 3, open-source calculator.

- 1. **Sampling technique:** Simple random sampling technique.
- 2. Inclusion criteria:
  - Patients with essential hypertension.
  - Hypertensive patients with age ≥18 years of both genders.
  - The major co-morbidities of diabetes mellitus, hypertensive heart diseases, hypertensive retinopathy, diabetic foot ulcer, acute pulmonary oedema, myocardial infarction, and coronary artery disease associated with all stages of hypertension.
  - Patients willing to participate in the study.
  - Patients willing to give consent.

#### Exclusion criteria

- Patients with Secondary hypertension
- Subjects with significant hepatic and renal diseases.
- Subjects who had psychiatric illness, who were chronically ill.
- Patients admitted for some ailments.

#### Ethical procedures

1. Maintenance of strict confidentiality of the data and participants of study.

Prior approval from institutional ethics committee (IEC) was received.

#### Data collection

- 1. After approval of IEC, the consent from patient, the procedures of actual data collection of research had been started.
- 2. In the OPD of the respective departments, proper demographic, personal, medical and family history had been taken. Associated co-morbidities had been asked too.
- 3. The measured blood pressure of the patients had been noted.
- 4. The prescription given by the doctors had been noted.

#### Data analysis

- 1. The data had been compiled, tabulated and analyzed with appropriate statistical techniques
- The data had been tabulated using Excel and Master sheet was made.
- 3. Percentages, proportions, bar graphs, pie charts, etc. methods of analysis were used for the evaluation.
- 4. Chi square test was applied using epi-info version 7.1.2.
- 5. P value of <0.05 is considered as statistically significant.

#### **Observations**

A total of 316 patients aged 18 years and above who had visited medicine OPD for the treatment of hypertension had been studied from 1<sup>st</sup> September 2019 to 30 November 2019. The participants of the study were in the range of age group from 30 to 81 years with the mean age of  $52.35 \pm 12.56$  years. Out of 316 patients 173 were males (55%) and 143 were females (45%). (Fig 1)



Fig 1 Gender distribution in study participants

**Table 1** Utilization of individual drugs

Individual Drugs	TOTAL	%
Calcium Channel Blockers	140	44.30
Aplha Blockers	8	2.53
Beta Blocker	102	32.28
K Channel Opener	19	6.01
Ace Inhibitors	14	4.43
Arbs	124	39.24
Loop Diuretic	36	11.39
Aldosterone Antagonists	16	5.06
Thiazide Diuretics	8	2.53
Others	3	0.95

We observed that Calcium channel blockers were the most commonly used drugs (44%) followed by ARBs (39%) and Beta blockers (32%).

**Table 2** Utilization of individual drugs among males and females.

Individual Drugs	M (173)	%	F (143)	%
Calcium Channel Blockers	69	39.88	72	50.35
Aplha Blockers	8	4.62	0	0.00
Beta Blocker	55	31.79	47	32.87
K Channel Opener	16	9.25	3	2.10
Ace Inhibitors	8	4.62	6	4.20
Arbs	71	41.04	52	36.36
Loop Diuretic	27	15.61	8	5.59
Aldosterone Antagonists	8	4.62	8	5.59
Thiazide Diuretics	3	1.73	6	4.20
Others	3	1.73	0	0.00

 $X^2 = 26.37$ , p = 0.002 (Significant)

The most commonly used drugs in males were ARBs (41%) and calcium channel blockers (40%) while in females the most commonly used drugs were calcium channel blockers (50%) and ARBs (36%). Beta blockers were being used by 32% males and 33% females. Antihypertensive drug utilization was significantly different in males and females (p = 0.002).

**Table 3** Drug combinations.

Drugs	Total	%
4 Drug Combination	3	0.95
3 Drug Combination	19	6.01
2 Drug Combination	47	14.87
Single Drugs	247	78.16

Single drugs were used by majority of the patients (78%) followed by 2 drug combinations (15%) and 3 drug combinations in 6% patients.

# **Drug Combination Example**

Combination of beta blockers with calcium channel blockers & ARBs & alpha blockers was seen in a 52 years old male patient having hypertension with Diabetes who was recently also complaining of Blurred vision. The drug combination patient was taking is –

ATENOLOL+AMLODIPINE+LOSARTAN+TAMSULOSIN

**Table 4** Drug combinations in males and females.

Drugs	M	%	F	%
4 Drug Combination	3	1.73	0	0.00
3 Drug Combination	8	4.62	11	7.69
2 Drug Combination	27	15.61	20	13.99
Single Drugs	135	78.03	112	78.32

 $X^2 = 3.84$ , p = 0.28 (NS)

There was not any significant difference in drug combinations in males and females.

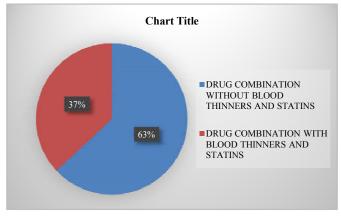


Fig 2 Drug combinations with and without blood thinners and statins.

3 Males were using 4 drug combinations (1.73%) while 8 were using 3 drug combination (4.62%) and 27 were using 2 drug combination antihypertensive therapy (15.61%). In females, 11 were using 3 drug combination (7.69%) and 20 were using 2 drug combination antihypertensive therapy (13.99%).

We had 200 patients who were not receiving any blood thinners and statins (63%), while rest 116 were receiving one of the blood thinners or statins or both (37%). (Fig 2)

#### **DISCUSSION**

Hypertension is one of the main non-communicable diseases in the world. India is also observing an increasing trend in hypertension cases both in urban and rural population. Indian population has prevalence of 12 to 17% in the rural and of 20 to 40% among urban adults.<sup>8</sup>

For complications like cardiovascular disease and the stroke, hypertension is one of the most important risk factors and it is also responsible for about 50% of cardiovascular diseases in the whole world. Effective treatment of hypertensive can be beneficial in these conditions. 8 - 10

The mean age of participants was  $52.35 \pm 12.56$  years. Out of total 316 patients 173 were males (55%) and 143 were females (45%).

HG Naik *et al*  $^{11}$  had 53% males and 47% females, with a mean age of 59.25 years. Similar to our study findings.

We observed that Calcium channel blockers were the most commonly used drugs (44%) followed by ARBs (39%) and Beta blockers (32%).

HG Naik *et al* <sup>11</sup> observed that CCBs and diuretics were the common drugs for the treatment of hypertension. The overall Drug utilization frequency showed that CCBs were the preferred drugs with 87.09% utilization followed by diuretics with 64.71%, ARBs with 10.75%.

Similar drug utilization results were also noted in studies conducted by Xavier et al. and Rachana et al. <sup>12, 13</sup>

The most commonly used drugs in males were ARBs (41%) and calcium channel blockers (40%) while in females the most commonly used drugs were calcium channel blockers (50%) and ARBs (36%). Beta blockers were being used by 32% males and 33% females. Antihypertensive drug utilization was significantly different in males and females (p = 0.002).

Datta S  $et\ al^{-14}$  found that male patients were given more ARBs as compared to females with a significant difference similar to our study.

Single drugs were used by majority of the patients (78%) followed by 2 drug combinations (15%) and 3 drug combinations in 6% patients.

HG Naik et al<sup>11</sup> reported that single antihypertensive drugs were used by majority of their patients (82%).

3 Males were using 4 drug combinations (1.73%) while 8 were using 3 drug combination (4.62%) and 27 were using 2 drug combination antihypertensive therapy (15.61%). In females, 11 were using 3 drug combination (7.69%) and 20 were using 2 drug combination antihypertensive therapy (13.99%).

Many authors reported similar findings with 70 to 83% patients using single drug therapy without any difference in the

number of drugs in combinations prescribed to the males or females.  $^{15-17}$ 

We had 200 patients who were not receiving any blood thinners and statins (63%), while rest 116 were receiving one of the blood thinners or statins or both (37%).

Tiwari H *et al*<sup>18</sup> also observed that 35% patients on antihypertensive drugs were receiving blood thinners or statins or both.

Similar findings were observed by Kaur P *el al*<sup>19</sup> and RH Babu *et al*<sup>20</sup>.

We observed that the use of generic medicines in our study was less (21%) as the majority of the patients were dependent on the branded medicines as prescribed by their physicians. If the standards of generic medicines can be improved with the proper surveillance by government, then the out-of-pocket expenditure on the branded medicines by the patients can be reduced. By encouraging generic medicines, it is possible to reduce the number of brands in the pharmacy, and it will also decrease the confusion while dispensing among the pharmacists. Pharmaceutical companies' strong promotional approach might be responsible for prescribing non-generic medicines economically when compared to generic medicines are always better than the branded drugs but with similar efficacy. <sup>11</sup>

# **CONCLUSION**

We conclude that the antihypertensive drug utilization should be studied on a larger scale in a multicentric study to know more about the drug utilization pattern in our hypertensive patients. We observed that Calcium channel blockers were the most commonly used drugs followed by ARBs and Beta blockers. We also observed that there were 22% patients using two or more drug combinations. We observed that the generic drug utilization is quite on lower side in our study, which is an area of improvement at national level. We conclude that there is a need for finding out the loopholes for the possible low compliance in antihypertensive treatment and necessary actions should be taken to prevent the possible complications by ensuring prompt and adequate treatment of hypertension.

Conflict of interest: None

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