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Drug Utilization Study in Patients Attending Hypertension Clinic of a Tertiary Care Hospital, Rajasthan, India

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Abstract

Background: Hypertension is a major public health problem in India, affecting a significant proportion of the population. Drug utilization research is important for assessing the rationality of drug treatment and for identifying areas for improvement. This study examined the drug utilization pattern of antihypertensive drugs in hypertensive patients at an Outpatient Department (OPD) in Udaipur, Rajasthan, India, based on JNC-8 classification. Materials and Methods: The observational cross-sectional study included 300 hypertension patients aged above 25 attending the hypertension clinic. Exclusions were made for inpatients, age < 25, uncertain diagnosis, pregnant/lactating mothers, and patients subsequently admitted after OPD visits. **Results:** The majority of affected patients were above 60 years old, with most having hypertension for 2-5 years, often accompanied by Type II Diabetes Mellitus. Oral administration was the primary drug delivery route. On average, patients received 1.93 antihypertensive drugs per encounter (range: 1 to 4), with an average of 5.82 drugs per encounter (range: 1 to 12). Losartan (72%) and amlodipine (46%) were the most prescribed drugs, with Angiotensin Receptor Blockers (ARBs) being the most prescribed drug class (79.3%), followed by Calcium Channel Blockers (CCBs) at 46.6%. The most common therapy was a two-drug combination (44.6%), followed by single-drug therapy (33%). Approximately 26.3% of prescriptions indicated potential drug interactions. **Conclusions:** This study provides valuable baseline data on the prescribing pattern of antihypertensive drugs. Rational prescribing practices are being followed, with the majority of patients being prescribed a combination of two or three antihypertensive drugs. However, there is a need to educate patients about the risks associated with uncontrolled high blood pressure and the benefits of lifestyle changes.

Keywords: Drug utilization; Hypertension; Lifestyle changes.

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INTRODUCTION

Hypertension is a chronic disease that can lead to serious health problems, including stroke, heart failure, and kidney disease. Once diagnosed, it is important to start long-term treatment and to have regular checkups. Uncontrolled hypertension can lead to serious long-term consequences.

The World Health Organization (WHO) defines drug utilization research as the study of the marketing, distribution, prescribing, and use of drugs in a society.¹ The main goal of drug utilization research is to assess the rationality of drug treatment. This involves auditing drug therapy methods to ensure that drugs are used rationally.

Significant differences in drug utilization have been observed between different countries, cities, and even within different health institutions within a country. These differences are likely due to changes in treatment patterns and trends over time.²

Regular studies on drug utilization patterns in different hospital settings and patient populations are essential to critically analyze recent hospital drug policies and to recommend guidelines for improving current drug usage patterns in the future. This is especially important in developing and resource-poor countries, such as India, where it ensures the optimal and appropriate use of scarce resources.^{3,4}

The study aimed to evaluate the drug utilization pattern of antihypertensive drugs in hypertensive patients attending the outpatient department of a tertiary care hospital in Udaipur, Rajasthan. The study included patients who were either newly diagnosed or were being followed up for their hypertension, according to the Eighth Joint National Committee (JNC-8) classification.

MATERIALS AND METHODS

A cross-sectional study was conducted by the department of Pharmacology in association with the department of Medicine at a tertiary care hospital in Udaipur, Rajasthan, India. The study was conducted over a period of 6 months, from July 2021 to December 2021. A total of 300 prescriptions were included in this study. Ethical Considerations

This study was approved by the Institutional Ethical Committee, and informed consent was obtained from all participating patients.

Inclusion Criteria

Patients who were above 25 years of age and had a confirmed diagnosis of hypertension were included in the study.

Exclusion Criteria

Indoor hypertension patients, individuals below 25 years of age, those with uncertain diagnosis, pregnant and lactating mothers, and patients who reported to the outpatient department but were subsequently admitted were excluded from the study.

Statistical Analysis

The data were analyzed using statistical tools such as frequencies, means, standard deviation (SD), and percentages. Various aspects were assessed, including the average number of anti-hypertension drugs prescribed per prescription, the relationship between patient demographics and prescription patterns, indicators for which antihypertensives were prescribed, percentage usage of various anti-hypertensives, dosage forms, fixed-dose combinations (FDCs), polypharmacy, and route of administration. Additionally, the drug utilization was measured using the Anatomical Therapeutic Chemical/ Defined Daily Dose (ATC/DDD) metric system.

RESULTS AND DISCUSSIONS

Age and sex distribution

Out of 300 patients, the prevalence of hypertension was higher in women, with 158 (52.7%) women and 142 (47.3%) men. These results align with a study conducted by Roobiya A et al (2018)⁵ but are in contrast to the findings of studies conducted by Supratim Dutta (2017)⁶ and Renoy Philip et al⁷, where hypertension was observed to be more common in men than in women. It can be inferred that different regions may exhibit varying demographic prevalence of hypertension due to social, economic, and dietary differences in different parts of the country. The majority of patients, 61.3%, belonged to the age group of >60 years, with a mean age of 62.7±9.33 years (See Table 1), which is similar to the findings of the study conducted by Zahrah Eslampanah (2016)8, where the mean age group of 200 patients was 57.9 years. It can be concluded that hypertension is more prevalent in individuals above 55 years of age. As people age, there is a decrease in the compliance of large elastic arteries, and aging also impacts pulse pressure and arterial compliance, which may contribute to the higher incidence of hypertension in the elderly population.

Table 1. Age and sex distribution

Age (years)	Men	Women	Total (%)
31-45	6 (2%)	8 (2.7%)	14 (4.7%)
46-60	36 (12%)	66 (22%)	102 (34%)
>60	100 (33.3%)	84 (28%)	184 (61.3%)
Total	142 (47.3%)	158 (52.7%)	300 (100%)

Regarding the history of hypertension, 63% of patients had a history of 2-5 years, 22.7% had a history of 6-10 years, and 4.7% had a history of more than 10 years. Among the patients, 79.3% were diagnosed as OLD cases who came for follow-up, while approximately 14.3% were diagnosed as OLD cases with poor control of hypertension. Additionally, around 6.3% of patients were newly started on anti-hypertensive therapy as their hypertension was not controlled by lifestyle modifications.

According to the latest classification of hypertension, 126 (42%) patients were classified as Grade 1 hypertension, 43 (14.3%) had Grade 2 hypertension, 77 (25.7%) had their blood pressure in the high normal range, and 54 (18%) had their blood pressure in the normal range. Additionally, 37% of patients were overweight with a BMI of 25-29.9, and 5% were obese.

Coexisting diseases

The majority of patients (28.3%) were suffering from concurrent Type 2 Diabetes Mellitus, followed by CAD (coronary artery disease) at 16.3%. Around 10.6% of patients were also diagnosed with hypothyroidism, and 8% had a history of CVA (Cerebrovascular Accident). Additionally, other commonly associated conditions included hypercholesterolemia, COPD (Chronic Obstructive Pulmonary Disease), Neuropathy, BPH (Benign Prostatic Hyperplasia), and arthritis.

These results were consistent with the study conducted by VA Saranya et al (2018)⁹. Diabetes and hypertension frequently coexist, and there is an overlap between their etiology and disease mechanisms. In a study by Saliha Mharchi et al. (2022), they found comparable outcomes. The findings indicated that individuals with diabetes had a 3.06 times higher likelihood of having hypertension, with an odds ratio (95% confidence interval) of 3.06 [2.11, 4.45].¹⁰

Hypertension and diabetes are two of the leading risk factors for atherosclerosis and its complications, such as heart attacks and strokes. The presence of both conditions can significantly increase the risk

of developing cardiovascular problems. It is crucial for healthcare professionals to be aware of this association and carefully manage patients with both diabetes and hypertension to reduce the risk of complications and improve overall health outcomes.

Total number of antihypertensive drugs prescribed per encounter

The majority of patients (134, 44.7%) were prescribed 2 antihypertensive drugs, while 99 patients (33.0%) received only 1 antihypertensive drug, and 55 patients (18.3%) were prescribed 3 antihypertensive drugs. A smaller group of 12 patients (4%) received 4 antihypertensive drugs. In our study, a total of 580 antihypertensive drugs were prescribed to 300 patients, resulting in an average of 1.93±0.82 antihypertensive drugs per encounter, with a range of 1 to 4. This finding is consistent with the results of a study conducted by Supratim Dutta in 2017, where a total of 511 antihypertensive drugs were prescribed during the study, leading to an average of 1.78 drugs per prescription.

Moreover, in our study, 96% of patients were receiving 2 or more total drugs as part of their prescribed treatment. The average number of total drugs per encounter was 5.82, with a wide range from 1 to 12.

Additionally, it was observed that 134 patients (44.6%) who had a duration of hypertension between 2 to 5 years were prescribed 2 or more different drugs, whereas only 14 patients (4.7%) with less than 2 years of hypertension history were receiving multiple drugs. (See Table 2).

Table 2. Duration of hypertension and total number of antihypertensive prescribed per encounter

Duration	No. of drugs	No. of patients	
	1	15 (5%)	
2	2	11 (3.7%)	
<2 years	3	2 (0.7%)	
	4	1 (0.3%)	
	1	55 (18.3%)	
2.5	2	82 (27.3%)	
2-5 years	3	43 (14.3%)	
	4	9 (3%)	
	1	21 (7%)	
6 10	2	37 (12.3%)	
6-10 years	3	8 (2.7%)	
	4	2 (0.7%)	
	1	8 (2.7%)	
. 10	2	4 (1.3%)	
>10 years	3	2 (0.7%)	
	4	0 (0%)	

Commonly used drug groups in study subjects

Among the antihypertensive drugs, the most prescribed drug class was Angiotensin Receptor Blockers ARBs (79.3%), followed by Calcium Channel Blockers CCBs (46.6%), Diuretics (39%), Beta-blockers (23%), and Angiotensin-Converting Enzyme Inhibitors ACEI (5%). Within the ARBs category, Losartan was the most prescribed drug (72%), while among Diuretics, Hydrochlorothiazide was the most commonly prescribed (35%). Amlodipine was the most prescribed drug in the CCB category (46%), and Metoprolol was the most prescribed drug among Beta-blockers (18.3%) (Table 3).

According to the new Indian Guidelines on Hypertension-IV 2019, ACEIs and ARBs are the preferred agents in young individuals (<60 years), while CCBs and diuretics are the preferred agents in those aged >60 years. In our study, a total of 580 antihypertensive drugs were prescribed, averaging around 1.93 prescriptions per patient. Among the antihypertensives, the most commonly prescribed drug class was ARBs (79.3%), followed by CCBs (46.6%), and Diuretics (39%).

However, the findings of previous studies differed. For instance, a study by Zahrah Eslampanah in 2015 reported that diuretics were the most prescribed class (40.14%). Similarly, Johan Pandyan J et al¹¹ in 2015 found that CCBs were the most prescribed antihypertensive medication. In contrast, a study by Supratim Dutta in 2017 reported Amlodipine as the single most prescribed antihypertensive agent (55.6%), with CCBs being the most prescribed class (72.3%), followed by ACEI/ARBs (34.9%). A study by Sorena Aurelian et al¹² in 2018 showed that Indapamide (85.7%), which belongs to the diuretic class, was the most prescribed antihypertensive in the elderly population.

Our study's results showing Losartan as the most prescribed antihypertensive align with the findings of Roobiya et al in 2018, where ARBs were the most common drug class (33.8%), and Telmisartan was the most prescribed drug (67.5%).

The variation in prescribing patterns among these studies could be attributed to differences in patient demographics, treatment regimens, and regional practices. It is noteworthy that the prescribing pattern has shifted from CCBs to ARBs after the advent of new guidelines from JNC-7, modifications from JNC-8, and the new Indian guideline on hypertension IV. Younger individuals with high renin hypertension are preferentially prescribed ACEIs/ARBs or newer beta

blockers, while older individuals with low renin hypertension are more likely to receive diuretics or CCBs as first-line agents. These guidelines aim to optimize treatment outcomes based on individual patient characteristics and comorbidities.

Utilization pattern of the various antihypertensive drugs

It was observed that multiple-drug therapy (74.9%) was more common than single-drug therapy (33%). (See Table 3). These findings are in contrast with the study conducted by Zahrah Eslampanah in 2016, where single-drug therapy (66%) was more prevalent than multidrug therapy (33%). Similarly, another study by Roobiya et al in 2018 reported that single-drug therapy (65.7%) was more common than combination therapy (34.3%).

Among the patients receiving single drug therapy, the most prescribed drug was LOSARTAN (16%), followed by AMLODIPINE (8.6%), and METOPROLOL (4.3%).

For patients receiving two drugs as therapy, the most commonly prescribed combination was LOSAR-TAN + AMLODIPINE (17%), followed by LOSAR-TAN + HYDROCHLOROTHIAZIDE (16.6%), and LOSARTAN + METOPROLOL (2.6%).

For patients receiving three drugs as therapy, the most prescribed combination was HYDROCHLO-ROTHIAZIDE + LOSARTAN + AMLODIPINE (7.6%), followed by LOSARTAN + AMLODIPINE + METOPROLOL (2.6%).

For patients receiving four drugs as therapy, the most prescribed combination was LOSARTAN + HYDROCHLOROTHIAZIDE + METOPRO-LOL + AMLODIPINE (2.7%).

Overall, the most prescribed combination in the patients was LOSARTAN + AMLODIPINE (17%), followed closely by LOSARTAN + HYDROCHLO-ROTHIAZIDE (16.6%).

These differences in results can be attributed to variations in patient profiles and the use of different treatment regimens based on associated comorbidities. It's worth noting that the ACCOMPLISH trial has demonstrated that combining ACEIs with CCBs is more effective than combining ACEIs with diuretics, making it a preferred combination in hypertension management.

Table 3. Utilization pattern of different antihypertensive drugs

Drugs	No. of patients (%)
SINGLE DRUG	99 (33%)
Hydrochlorothiazide	3 (1%)
Losartan	48 (16%)
Telmisartan	6 (2%)
Metoprolol	13 (4.3%)
Amlodipine	26 (8.6%)
Enalapril	3 (1%)
TWO DRUG COMBINATION	134 (44.6%)
Hydrochlorothiazide + Losartan	50 (16.6%)
Hydrochlorothiazide + Atenolol	1 (0.3%)
Hydrochlorothiazide + Telmisartan	5 (1.6%)
Metoprolol + Losartan	8 (2.6%)
Metoprolol + Enalapril	5 (1.6%)
Metoprolol + Telmisartan	3 (1%)
Amlodipine + Losartan	51 (17.0%)
Amlodipine + Atenolol	3 (1%)
Amlodipine + Telmisartan	1 (0.3%)
Amlodipine + Enalapril	3 (1%)
Losartan + Spironolactone	4 (1.3%)
THREE DRUG COMBINATIONS	55 (18.3%)
Hydrochlorothiazide + Losartan + Atenolol	4 (1.3%)
Hydrochlorothiazide + Losartan + Amlodipine	23 (7.6%)
Hydrochlorothiazide + Losartan + Metoprolol	4 (1.3%)
Hydrochlorothiazide + Losartan + Furosemide	2 (0.6%)
Hydrochlorothiazide + Metoprolol + Amlodipine	3 (1%)
Losartan + Metoprolol + Amlodipine	8 (2.6%)
Losartan + Atenolol + Amlodipine	2 (0.6%)
Losartan + Spironolactone + Furosemide	2 (0.6%)
Amlodipine + Metoprolol + Enalapril	1 (0.3%)
Amlodipine + Metoprolol + Telmisartan	3 (1%)
Amlodipine + Atenolol + Telmisartan	1 (0.3%)
Amlodipine + Cilindipine + Telmisartan	2 (0.6%)
FOUR DRUG COMBINATIONS	12 (4%)
Hydrochlorothiazide + Losartan + Amlodipine + Furosemide	1 (0.3%)
Hydrochlorothiazide + Metoprolol + Losartan + Amlodipine	8 (2.7%)
Hydrochlorothiazide + Losartan + Amlodipine + Atenolol	2 (0.7%)
Hydrochlorothiazide+ Atenolol +Telmisartan +Amlodipine	1 (0.3%)

Comparison of dose frequencies of the various antihypertensive drugs

The drug HYDROCHLOROTHIAZIDE was mostly given in an Once Daily OD dose (92.3%) compared to the twice daily BID dose (7.61%). Similarly, the drug LOSARTAN was predominantly given in an OD dose (75.46%) rather than the BD dose (24.5%). AMLODIPINE was also mostly prescribed in an OD dose (78.9%) as opposed to the BD dose (21%). Likewise, METOPROLOL was predominantly prescribed in an OD dose (98.18%) compared to the BD dose (1.81%). On the other hand, the drugs TELMISARTAN, ENALAPRIL, and ATENOLOL were exclusively prescribed in an OD dose.

Modifiable risk factors of hypertension

It was found that approximately 12% of patients smoked tobacco, around 14.3% of patients consumed alcohol, and approximately 5% of patients consumed both alcohol and tobacco. Additionally, around 38% of patients were categorized as overweight. In the study done by Saranya et al (2018) they found out that 32.4% were smokers, 24.5% were alcoholic.

Drug-Drug Interactions

Upon analyzing the 300 prescriptions, it was found that approximately 79 (26.3%) of them had potential drugdrug interactions. Among these interactions, around 3 (1%) were classified as MAJOR, 41 (13.66%) as MODERATE, and approximately 35 (11%) were considered minor interactions.

In the study conducted by Saranya et al. (2018), it was found that prescriptions with drug interactions accounted for approximately 54.9% of the cases. This highlights the importance of having proper knowledge about drug interactions among healthcare professionals. Clinicians must stay updated on the current practice guidelines to ensure a smoother patient experience and minimize potential complications arising from drug interactions. (See Tables 4 and 5)

Percentage of drugs prescribed from essential medicine list

Out of the 39 drugs used, 22 (56.41%) were prescribed from the WHO Model List of Essential Medicines, 22nd list of 2021, and 24 (61.5%) were prescribed from the National List of Essential Medicines of India, 2015.

Prescribed Daily Dose (PDD) and Defined Daily Dose (DDD) of antihypertensive drugs

The prescribed daily doses of various antihypertensive drugs were recorded as follows: Hydrochlorothiazide (13.45mg), Losartan (60.76mg), Telmisartan (40mg), Amlodipine (5.96mg), Atenolol (50mg), Metoprolol (38.63mg), Enalapril (3.33mg), Cilnidipine (10mg), Furosemide (40mg), and Spironolactone (31.25mg).

The PDD/DDD ratio ranged between 0.25 and 1.21, with Losartan having the maximum ratio of 1.21, followed by Amlodipine (1.19), Telmisartan (1), Cilnidipine (1), Furosemide (1), Atenolol (0.66), Hydrochlorothiazide (0.53), Spironolactone (0.41), Enalapril (0.33), and Metoprolol (0.25) (See Table 6).

When the PDD/DDD ratio is either less than or greater than one, it may indicate that there is either under or over utilization of drugs. Nevertheless, it is important to note that the PDD can vary according to patient and disease factors.

CONCLUSION

This study has provided valuable baseline data on the prescribing pattern of antihypertensive drugs in hypertensive patients in Udaipur, Rajasthan, India. The data showed that rational prescribing practices are being followed, with the majority of patients being prescribed a combination of two or three antihypertensive drugs.

However, there is a need to educate patients about the risks associated with uncontrolled high blood pressure and the benefits of lifestyle changes. It is also important to emphasize the importance of long-term adherence to prescribed treatment and regular monitoring for effective hypertension management.

Further research is needed to investigate the factors that contribute to non-compliance with antihypertensive medications in hypertensive patients. Additionally, research is needed to evaluate the effectiveness of different interventions for improving patient adherence to antihypertensive medications.

Table 4. Drug-Drug Interactions

S. No	Drug combination	Effects	Severity
1	Spironolactone + Telmisartan	Life Threatening Hyperkalemia	Major
2	Spironolactone + Enalapril	Hyperkalemia	Major
3	Enalapril + Aspirin	Decreased Ramipril Effectiveness	Moderate
4	Enalapril + Diclofenac	Decreased Antihypertensive Effect	Moderate
5	Metoprolol + Amlodipine	Hypotension / Bradycardia	Moderate
6	Amlodipine + Clopidogrel	Decreased Response To Clopidogrel	Moderate
7	Amlodipine +Diclofenac	Increased Risk Of Gi Hemorrhage	Minor
8	Atenolol + Aspirin	Decreased Efficacy Of Atenolol	Minor
9	Furosemide + Aspirin	Decreased Efficacy Of Diuretics	Minor
10	Digoxin + Spironolactone	Digoxin Toxicity	Minor
11	Aspirin + Spironolactone	Hyperkalemia	Minor
12	Metoprolol + Aspirin	Decreased Efficacy Of Metoprolol	Minor

Table 5. Drug-Drug interactions their severity

Prescriptions screened	No. of prescriptions	
Prescriptions with drug interactions	79 (26.3%)	
Prescriptions without drug interactions	221 (73.66%)	
Severity	Number of interactions	
Major	3 (1%)	
Moderate	41 (13.66%)	
Minor	35 (11%)	

Table 6. ATC, PDD and DDD of antihypertensive drugs

Drug	ATC code	PDD	DDD	PDD/ DDD ratio
Hydrochlorothiazide	C03AA03	13.45mg	25mg	0.53
Losartan	C09CA01	60.76mg	50mg	1.21
Telmisartan	C09CA07	40mg	40mg	1
Amlodipine	C08CA01	5.96mg	5 mg	1.19
Atenolol	C07AB03	50mg	75mg	0.66
Metoprolol	C07AB02	38.63 mg	150 mg	0.25
Enalapril	C09AA02	3.33mg	10mg	0.33
Cilnidipine	C08CA14	10mg	10mg	1
Furosemide	C03CA01	40mg	40mg	1
Spironolactone	C03DA01	31.25	75mg	.41

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