International Journal of Basic & Clinical Pharmacology
Mahfooz MS et al. Int J Basic Clin Pharmacol. 2025 Sep;14(5):746-753
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20252571

Original Research Article

Effectiveness, adverse drug reactions and adherence among hypertension patients in department of general medicine at Integral Institute of Medical Science and Research: a prospective observational study

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Received: 22 May 2025
Revised: 20 July 2025
Accepted: 21 July 2025

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ABSTRACT

Background: This study aimed to evaluate the drug effectiveness, adverse drug reactions and adherence among hypertensive patients. Additionally, we aimed to determine the clinical characteristics and the risk factors.
Methods: This six-month prospective observational study was jointly conducted by Integral University's department of pharmacy and Medicine at Integral Institute of Medical Sciences and Research, Lucknow. The investigation involved 100 hypertensive patients from both inpatient (IPD) and outpatient (OPD) departments. Collected data were analysed through Microsoft Excel using descriptive statistical methods.
Results: The study population comprised 100 hypertensive patients (38 male, 62 female). Analysis showed 82% treatment efficacy, with telmisartan+amlodipine combination therapy achieving significant blood pressure reduction (11.7 mmHg). Notably, ADRs were monitored via active surveillance and patient interviews; suspected events were assessed using the Naranjo causality scale. Medication compliance reached 84%, particularly with once-daily regimens of amlodipine 5 mg and telmisartan 40 mg (marketed as Telvas/Telma). These findings demonstrate the clinical efficacy and safety profile of current antihypertensive protocols, emphasizing the importance of appropriate drug selection and dosing schedules.
Conclusions: The study confirmed the therapeutic effectiveness, strong adherence rates, and excellent safety profile of antihypertensive treatments, particularly telmisartan and amlodipine. These outcomes validate existing prescription patterns while providing real-world evidence for hypertension management strategies. Ongoing monitoring of treatment response and patient compliance remains crucial for maintaining optimal cardiovascular health outcomes.

Keywords: Antihypertensive therapy, Drug safety monitoring, Hypertension management, Real-world evidence,

INTRODUCTION

Antihypertensive medications often provoke adverse drug reactions (ADRs), which can restrict therapeutic options and undermine patient adherence, consequently impeding effective blood pressure regulation. It was thought that the disparities in the rates of adverse symptoms across different classes of antihypertensive drugs were likely responsible for the varied discontinuation rates.[1] Each year, the World Health Organization reports that a minimum of 7.1 million individuals succumb to elevated blood pressure.[2] Adverse events linked to drug treatment are typically seen as diminishing medication adherence, yet certain patients perceive these symptoms as evidence

of drug efficacy. If drugs perceived as effective are more likely to be consumed, adverse events might actually boost adherence. However, the extent to which patients view adverse events as signals of drug effectiveness remains uncertain.[3] According to the World Health Organisation (WHO), adherence occurs when a person follows a doctor's recommendations for medication take-along behaviour, diet, and/or lifestyle modifications.[4] The same condition is referred to as treatment compliance, treatment adherence, or adherence to treatment regimen. The degree of agreement between a patient's behaviour in relation to their treatment plan and the advice of a medical professional is known as adherence.[5] In developed nations, the estimated percentage of patients with chronic diseases who adhere to long-term treatment is 50%. In underdeveloped nations, the figures are even lower.[6] Several studies have reported that the biggest challenge of hypertension is treatment adherence, and poor adherence, the most important cause of uncontrolled blood pressure.[7]

Hypertension is defined as elevation of arterial blood pressure (BP). High blood pressure often produces no symptoms, but it can increase the risk of heart disease, stroke, and other serious health conditions. It is a primary risk factor for cardiovascular disease, including stroke, heart attack, heart failure, and aneurysm.[8]

The European Society of Cardiology (ESC) Guidelines on the Detection, Evaluation and Treatment of High Blood pressure classifies adult BP according to the table given below:[9]

Table 1: Classification of hypertension.

Classification	Systolic (mmHg)	Diastolic (mmHg)
Normal	120-129	80-84
Optimal	<120	<80
High normal	130-139	85-89
Grade 1	140-159	90-99
Grade 2	160-179	100-109
Grade 3	≥180	≥110
Isolated systemic hypertension	≥140	<90

Types of hypertensions

It is broadly categorized into two major types based on etiology: primary (essential) hypertension and secondary hypertension. Primary hypertension, which lacks a specific identifiable cause, results from a complex interplay of genetic predisposition and environmental influences. It constitutes approximately 90-95% of adult hypertension cases and typically progresses gradually over time. Common risk factors associated with primary hypertension include advancing age, obesity, high sodium intake, sedentary lifestyle, and family history of elevated blood pressure.[10] Due to its widespread prevalence, primary hypertension significantly contributes to the global burden of cardiovascular diseases. In contrast, secondary hypertension accounts for about 5-15% of cases and arises from underlying, often correctable, medical conditions.[11] Etiologies include renal parenchymal and renovascular diseases, endocrine abnormalities such as primary hyperaldosteronism, Cushing's syndrome, or pheochromocytoma, as well as structural issues like coarctation of the aorta and lifestyle-related causes such as medication misuse or obstructive sleep apnea.[11] Prompt identification of secondary hypertension is clinically essential, as effective treatment of the underlying cause such as surgical intervention or targeted pharmacotherapy can result in normalization of blood pressure.[12] Patients presenting with early-onset, treatment-resistant, or rapidly worsening hypertension, or with biochemical abnormalities such as hypokalaemia, should be evaluated for secondary causes.[12]

METHODS

This was a prospective observational study conducted over a period of six months, from 08 September 2023 to 08 March 2024, at the Integral Institute of Medical Sciences and Research (IIMSR), Integral University, Lucknow-226026, India. The study involved collaboration between the department of medicine and the faculty of pharmacy. Both inpatient (IPD) and outpatient (OPD) departments were included as study sites. Effectiveness was defined as achieving target BP (<140/90 mmHg) at follow-up or a ≥10 mmHg reduction in mean systolic blood pressure from baseline.

Sample size calculated using

$$N = \frac{Z^2 p(1-p)}{d^2}$$

Z=1.96 (95% CI), p=0.07, d=0.05 giving n ≈ 100.04 (rounded to 101). Due to feasibility, 100 eligible patients were enrolled; the one-patient shortfall is acknowledged as a limitation. Data were analysed using SPSS. Continuous variables are presented as mean±SD, categorical as n (%). Baseline vs follow-up BP were compared using paired t-test (or Wilcoxon if non-normal); two-sided p<0.05 was considered significant. Blood pressure measurements were taken in the seated position after 5 minutes rest, using an automated sphygmomanometer. Two readings were averaged for analysis; all measurements were performed by trained nursing staff. Adverse drug reactions were identified via active surveillance: daily chart review, structured patient interviews at each visit, and spontaneous reports.

Suspected events were evaluated using the Naranjo scale. Medication adherence was measured using the 8-item Morisky Medication Adherence Scale (MMAS-8); scores were categorized per standard cut-offs. A total of 100 eligible hypertensive patients were enrolled based on defined inclusion and exclusion criteria. Ethical approval was obtained from the institutional research board and

institutional ethics committee, and the study was conducted in full compliance with WHO guidelines. Prior to participation, both oral and written informed consent was obtained from each patient or their caregiver. To maintain confidentiality, all data were anonymized.

Inclusion and exclusion criteria

The inclusion criteria required patients to be diagnosed with hypertension, regardless of gender, and aged above 18 years. Pregnant and lactating women, as well as patients with comorbidities such as diabetes mellitus and asthma, were also considered. Exclusion criteria included patients with cognitive or psychological impairments, those not diagnosed with hypertension, individuals unable to adhere to treatment plans, and patients with a history of substance abuse.

Data collection was carried out using multiple sources, including: Physician's prescribing records, Patient's medication charts, Patient's progress and assessment charts, Nurse assessment documentation.

RESULTS

General characteristics of study population

Around 100 patients were diagnosed with Hypertension at Integral Institute of Medical Science and Research (IIMSR), Lucknow, during a study period of 6 months and their general characteristics are as follows. There were 62 females and 38 males, 7 were smokers, 10 were alcohol consumer, and 18 were tobacco consumer.

Table 2: General demographical characteristics of study population.

Gender	Number of patients	Percentage
Male	38	38
Female	62	62
Employment status		
Emplyoed	28	28
Unemployed	72	72
Family history of HTN		
Present	13	13
Absent	87	87
Surgical history		
Yes	6	6
No	94	94
Allergies		
Present	1	1
Absent	99	99

Age range of study population utilizing antihypertensive drugs

Patients aged 51-60 had the highest risk of hypertension (29%), with the 41-50 age group next at 25%.

Table 3: Age range of study population utilizing antihypertensive drugs.

Age range (in years)	Number of patients	Percentage
20-30	1	1
31-40	14	14
41-50	25	25
51-60	29	29
61-70	22	22
71-80	8	8
81-90	1	1
91-100	0	0

Types of therapy, route of administration and risk factors in study population

Among 100 patients, 57% were undergoing combination therapy, while 91% received medication solely through oral administration, and 95% had identifiable risk factors.

Table 4: Types of therapy, route of administration and risk factors.

Type of therapy	Number of patients	Percentage
Single	43	43
Combination	57	57
Route of administration		
Only oral	91	91
Intravenous with oral	9	9
Risk factors		
Present	95	95
Absent	5	5

Class of drugs prescribed to study population

The list below of 100 prescriptions, mentions the list of commonly used agents from different classes of drugs. calcium channel blocker (69%) and angiotensin receptor blocker (64%) were found.

Table 5: Classification of medications prescribed.

Classification of medications prescribed	Number of patients
Angiotensin receptor blocker	64
Calcium channel blocker	69
Diuretic	26
Beta adrenergic blocker	17
Central sympatholytic	3
Ace inhibitor	1

Brands name of drugs used in study population

Telvas-AM was prescribed to 23% of patients, while Telma-AM and DYTOR were each prescribed to 13% of patients (Table 6).

Table 6: Brand name of drugs used.

Brand name of medications	Number of patients
Telma-AM (telmisartan and amlodipine)	13
Telvas-AM (telmisartan and amlodipine)	23
Telvas-40 (telmisartan)	11
Telma-40 (telmisartan)	9
Amlong (amlodipine)	10
Amlokind (amlodipine)	10
Newtel-AMH (amlodipine, telmisartan and hydrochlorothiazide)	2
Lasix (furosemide)	9
CTD-MT (telmisartan, chlorothiazide and metoprolol)	1
Cortel-AM (telmisartan and amlodipine)	2
Arkamine (clonidine)	3
Cilacar (cilnidipine)	2
Ciplar-LA (propranolol)	5
Nicardia (nifedipine)	6
Dytor (torsemide)	13
MET-XL (metoprolol succinate)	7
Dytor plus (torsemide and spironolactone)	1
Telmikind 40 (telmisartan)	1
Amlodep-AT (amlodipine and atenolol)	1
Telma-beta (telmisartan and metoprolol)	1
Telvas-beta (telmisartan and metoprolol)	1
Tenoric (atenolol and chlorthalidone)	1
Amlob-5 (amlodipine)	2
Telma-trio (telmisartan, chlorothiazide and cilnidipine)	1
Metpure-XL (metoprolol succinate)	1
Metolar-XR (metoprolol succinate)	1

Generic name of drugs used in study population

The most commonly prescribed combination in terms of generic names was amlodipine + telmisartan (38%) and amlodipine was given (28%) (Table 7).

Clinical characteristics

Several clinical characteristics such as comorbidities, duration of treatment etc. signify how the severity of hypertension plays a crucial role in determining drug therapies (Table 8).

Main parameters of drugs assessed in the study population

Out of 100 patients' adherences were found in 84% patients, Drug effectiveness was found in 82% patients and No ADRs were detected during the study follow-up period using active surveillance and Naranjo assessment (Table 9).

Drug effectiveness based on mean reduction in blood pressure

Table 10 ranks antihypertensive medications by their effectiveness in lowering blood pressure.

Table 7: Generic name of drug used.

Generic name of medications	Number of patients	Percentage
Amlodipine	28	28
Telmisartan	21	21
Amlodipine and telmisartan	38	38
Telmisartan and metoprolol	2	2
Clonidine	3	3
Cilnidipine	2	2
Metoprolol	9	9
Nifedipine	6	6
Propranolol	5	5

Continued.

Generic name of medications	Number of patients	Percentage
Ramipril and metoprolol	1	1
Furosemide	9	9
Chlorthalidone, telmisartan and metoprolol	1	1
Torsemide	13	13
Torsemide and spironolactone	1	1
Telmisartan, amlodipine and hydrochlorthiazide	3	3
Atenolol and amlodipine	1	1

Table 8: Clinical characteristics of study population.

Clinical characteristics	Numbers of patients	Percentage
Comorbidities		
Present	43	43
Absent	57	57
Types of comorbidities		
Diabetes mellitus	34	34
Cad	7	7
Hypothyroidism	9	9
Hyperlipidemia	1	1
CAV	1	1
Number of medications		
One	57	57
Two	31	31
More than two	12	12
Treatment duration		
0-1 year	63	63
1-5 years	28	28
>5 years	9	9
Lifestyle factors		
Alcohol	10	10
Tobacco	18	18
Smoking	17	17
Risk factors		
Genetics	4	4
Unhealthy diet	31	31
Stress	73	73
Comorbidities	52	52
High potassium intake	-	-
Low sodium intake	-	-
Obesity	5	5

Table 9: Main parameters of drugs assessed in the study population.

Adherence to medication	Number of patients	Percentage
Present	84	84
Absent	16	16
Drug effectiveness		
Present	82	82
Absent	18	18
Adverse drug reactions		
Present	0	0
Absent	100	100

Table 10: Drug effectiveness based on mean reduction in blood pressure.

Generic name of medications	Number of patients	Mean reduction in systolic BP	Mean reduction in diastolic BP
Amlodipine and telmisartan	39	11.71 mmHg	6.32 mmHg
Amlodipine	29	11.61 mmHg	7.14 mmHg
Telmisartan	21	13.09 mmHg	6.66 mmHg
Torsemide	15	6.15 mmHg	3.84 mmHg
Metoprolol	9	14.4 mmHg	7.22 mmHg
Furosemide	9	9.44 mmHg	5 mmHg
Nifedipine	6	3.33 mmHg	1.67 mmHg
Propranolol	5	14 mmHg	7 mmHg
Telmisartan, amlodipine and hydrochlorothiazide	3	8.33 mmHg	5 mmHg
Telmisartan and metoprolol	2	10 mmHg	5 mmHg
Cilnidipine	2	7.5 mmHg	5 mmHg
Clonidine	3	0 mmHg	0 mmHg
Ramipril and metoprolol	1	20 mmHg	15 mmHg
Atenolol and amlodipine	1	15 mmHg	5 mmHg
Torsemide and spironolactone	1	15 mmHg	10 mmHg
Chlorthalidone, telmisartan and metoprolol	1	30 mmHg	10 mmHg

DISCUSSION

As a common chronic illness, hypertension needs to be carefully managed to avoid consequences. In particular, the prevalence of adverse drug reactions (ADRs), patient demographics, associated comorbidities, adherence, and drug effectiveness was examined, alongside the results of a prospective observational study on drug effectiveness and adherence in hypertensive patients. In this study, it was observed that 84 patients showed adherence, and 82 showed effectiveness. Notably, there were no adverse drug reactions found among study population.

In contrast to a similar study that had 320 patients and 75 ADRs in Aurangabad, Maharashtra and in our study, adherence was 84% but comparing with the study in Brazil it was 45%.[13] For effectiveness we have taken mean decrease in systolic (SBP) and diastolic blood pressure (DBP) achieved by each drug or combination.[14] Different drug combinations lower blood pressure by 20 to 25 systolic and 10 to 15 diastolic mmHg. Response varies according to weight, sex, and ethnicity, which helps with better drug selection depending on baseline blood pressure. This implies that rules should be updated in light of the available data. These results suggest that the management of hypertensive patients is a more difficult and involved endeavour.

The study highlighted that male patient had a lower admission rate (38%) compared to females (62%). Additionally, the study found that patients in the age ranges of 51-60 and 41-50 were more prone to developing hypertension, with 29% and 25% prevalence respectively. The study identified comorbid conditions such as type 2 diabetes, obesity, hypothyroidism, hyperlipidaemia. These findings reinforce the existing knowledge that hypertension is often associated with other health conditions. The presence of multiple comorbidities can contribute to the complexity of hypertension management and increase the likelihood of effectiveness, ADR and adherence. These results support the notion that hypertension is frequently linked to other medic disorders.[15] Multiple comorbidities can enhance the likelihood of effectiveness, adverse drug reaction, and adherence while also adding complexity to the management of hypertension. Similar outcomes from Saudi Arabia and Ethiopia also showed comorbidity as a factor influencing adherence.[16]

Variations in the use of antihypertensive medications were noted by the study. The most often prescribed medications were telmisartan (21%) and amlodipine (28%) with telmisartan-amlodipine combination therapy being used often. A similar study conducted in a tertiary care teaching hospital Chidambaram, south India, where captopril was the most widely provided antihypertensive drug.[17] These differences in drug use trends may be caused by things like regional prescribing procedures, medicine availability, and treatment recommendations.

In the current study, only two types of routes of administration were observed: oral and intravenous (i.v.). Amlodipine was most commonly administered orally, while furosemide topped the list for i.v. administration. This finding highlights the preference for oral administration in hypertensive patients, emphasizing the convenience and patient adherence associated with this route. The demands and features of each patient should be taken into consideration while selecting the right drugs and delivery methods.

To sum up, this comparative analysis of a prospective observational study on medication adherence, adverse drug reactions, and effectiveness in hypertension patients offers insightful information. It also highlighted how crucial it is to take comorbid illnesses into account and personalize treatment regimens. The results add to the body of knowledge already in existence and can help medical practitioners treat hypertension patients as best they can.

It is important to recognise the various limitations of this study. First off, the results may not be as broadly applicable to larger, more varied populations due to the small sample size (n=100). The study's six-month duration at a single centre may have introduced regional prescribing bias and limited the variety of patient profiles.

Second, considering the known frequency of mild to moderate adverse drug reactions (ADRs) in antihypertensive therapy, the lack of reported ADRs may reflect underreporting rather than true absence. However, in this study ADRs were actively monitored by daily chart review and structured patient interviews at each visit, and suspected events were assessed using the Naranjo causality scale by the clinical pharmacist. Despite active surveillance, no ADRs were detected; this result likely reflects the limited sample size (n=100), relatively short follow-up for delayed reactions, and the possibility of transient or unreported mild events. Therefore, these findings should be interpreted cautiously and confirmed in larger studies with longer follow-up and robust pharmacovigilance.

Exploring relationships between demographic variables, comorbidities, and treatment outcomes was further limited by the use of descriptive statistical methods exclusively, without inferential analysis or regression modelling. Furthermore, rather than using validated measures like the Morisky medication adherence scale (MMAS), which may introduce recall or reporting bias, adherence was evaluated indirectly (using patient self-report and prescription records).

Last but not the least, although the study found that the drug was effective in lowering mean blood pressure, it failed to stratify results according to pharmacogenomics, body weight, or renal function, all of which could affect therapeutic response.

To provide a more thorough assessment of hypertension management techniques, future studies should take into account multicentric designs, larger samples, and standardised instruments for ADR detection and adherence measurement.

CONCLUSION

This study evaluated antihypertensive therapy in 100 patients (38 males, 62 females), demonstrating excellent treatment adherence (84%) and clinical effectiveness (82%) without reported adverse reactions. The prescription analysis revealed a clear preference for combination therapy, with 57% of patients receiving two antihypertensives. telmisartan (21%), amlodipine (28%), and particularly their fixed-dose combination (38%) emerged as the most frequently prescribed medications, reflecting current hypertension management guidelines favouring RAAS inhibitors with calcium channel blockers.

The 51-60 age group showed the highest hypertension prevalence, aligning with established epidemiological patterns. Administration routes were predominantly oral (notably for telmisartan+amlodipine combinations), with intravenous Furosemide reserved for specific clinical scenarios. Market trends were evident in the frequent prescription of branded combinations like Telvas-AM (23%) and Telma-AM (13%), which collectively accounted for nearly half of the top prescribed formulations. These findings underscore the real-world clinical preference for evidence-based drug combinations while maintaining high patient compliance and therapeutic safety.

ACKNOWLEDGEMENTS

Authors would like to thank to Prof. S. W. Akhtar, hon'ble chancellor integral university and professor (Dr.) Syed Misbahul Hasan, dean faculty of pharmacy, Integral University, Lucknow, India for providing with proper facilities and academically rich scientific environment for the research in the university's infrastructure to explore and study extensively into clinically relevant fields.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee IIMSR Integral University, Lucknow with certificate number IEC/IIMSR/2023/47 dated 17/08/2023

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Cite this article as: Mahfooz MS, Husain M, Roy M, Fatima K, Akhter MS, Khan MT. Effectiveness, adverse drug reactions and adherence among hypertension patients in department of general medicine at Integral Institute of Medical Science and Research: a prospective observational study. Int J Basic Clin Pharmacol 2025;14:746-53.