

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20262872>

## Original Research Article

# A cross-sectional study on hospital-based evaluation of adverse drug reactions and drug-related issues in hypertensive patients

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**Received:** 11 July 2026

**Accepted:** 12 August 2026

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## ABSTRACT

**Background:** The primary goal of the study was to evaluate adverse drug reactions and drug-related problems in patients with hypertension at the tertiary care hospital in Lucknow. The secondary goal was to assess the treatment patterns and outcomes for these patients at the same hospital.

**Methods:** This was a prospective, observational study. A total of 100 patients who met the inclusion and exclusion criteria were recruited from the outpatient and inpatient departments of the general medicine division at the Integral Institute of Medical Science and Research Hospital. Patients' data were evaluated to identify Drug-Related Problems using a systematic, evidence-based approach.

**Results:** Data from 100 patients were collected in this study. The main identified drug-related problems affecting blood pressure control included failure to receive medications, drug-drug interactions and untreated indications. A total of 3 adverse drug reactions (ADRs) were observed among the 100 cases. Hyperkalemia was observed in 02 patients (28.6%), pedal edema in 02 patients (28.6%) and dry cough in 03 patients (42.9%).

**Conclusions:** Patients taking anti-hypertensive medications frequently encounter adverse drug reactions. Our study recommends regular ADR monitoring in hospital settings to encourage rational medication prescribing.

**Keywords:** Adverse drug reaction, Cross-sectional study, Hypertension

## INTRODUCTION

Drug-related issues pose a significant challenge for healthcare providers. It severely undermines management effectiveness, making this a critical issue in population health from both the value-of-life and health-burden perspectives.<sup>1</sup> Problems related to drugs in hypertensive patients can delay or hinder their ability to reach the desired therapeutic outcomes. It has been attributed to unnecessary over-prescription of medication, significant deterioration of diseases, unwarranted increases in hospital admission rates and longer hospital stays, resulting in a major medical crisis load. As a result,

many patients do not receive the full benefits of healthcare, leading to poorer health outcomes, lower quality of life, higher healthcare costs and decreasing public trust in health systems.<sup>2,3</sup>

Therefore, the objective of this study was to determine the pattern and extent of drug-related problems in the study hospital and to identify risk factors for these issues problems.<sup>3</sup> Hypertension is defined as persistently elevated blood pressure, with systolic blood pressure (SBP) and diastolic blood pressure (DBP) readings of 140/90 mmHg or higher. Hypertension is a major global public health challenge because of its high prevalence and

its role as a risk factor for cerebrovascular, cardiovascular and renal diseases. It is a silent killer disease in both developed and developing countries world.<sup>4</sup> It is an essential global public health challenge due to its high frequency and risk factor for cerebrovascular, cardiovascular and renal issues disease.<sup>2,5,6</sup> Adverse drug reactions related to medications are common and pose serious health issues, which can limit treatment options, compliance and even lead to discontinuation of treatment. Hypertension is a chronic condition that is considered one of the most significant cardiovascular risk factors. For managing hypertension, a wide range of anti-hypertensive agents are available as either single or combination therapies to achieve a target blood pressure in patients. In contrast, the combination treatment raises the risk of triggering an adverse drug reaction.

Patients with hypertension often have other medical conditions such as hyperlipidemia, impaired glucose metabolism and renal impairment, which contribute to a higher rate of cardiovascular morbidity and mortality.<sup>1</sup> The World Health Organization (WHO) estimates that about 62.0% of the burden from cerebrovascular disease and 49.0% of ischemic heart disease worldwide are due to suboptimal blood pressure control levels.<sup>2,6-8</sup> High blood pressure is estimated to cause 7.1 million deaths each year, representing 13.0% of all deaths globally.<sup>2,3,5,7</sup>

The primary objective of the study was to assess the adverse drug reactions and drug-related problems in patients with hypertension at a tertiary care hospital in Lucknow. The secondary objective of the study was to evaluate the treatment pattern and outcomes of patients with hypertension at this hospital.

## METHODS

A prospective cross-sectional observational study was conducted across various inpatient (IPD) and outpatient (OPD) departments at the Integral Institute of Medical Sciences and Research (IIMS&R) in Lucknow, India, over a 6-month period (November 2021-May 2022). During the study, 100 prescriptions were analyzed.

Patient demographic details such as name, age, sex, place and weight were recorded on a specially designed daily patient data collection form. Additionally, information on diagnosis, patient complaints, number of drugs prescribed, social history and the generic or brand names of medications was documented using the same form.

### *Inclusion criteria*

Patients with hypertension who have provided written informed consent. All patients who are 18 years or older. Participants on antihypertensive treatment for at least one month with regular outpatient follow-up. No gender bias. Pregnant and breastfeeding patients were also included. All patients with hypertension and other co-morbidities were also included.

### *Exclusion criteria*

Patients who had not started anti-hypertensive drugs. Patients who did not responded. The patients who are interviewed and unconscious. Mentally unstable patients with hypertension. Patients with drug abuse were excluded from this study.

### *Parameters assessed*

The parameters listed below were evaluated.

Types of prescribed antihypertensive medications. Average number of antihypertensive medications per prescription. Route (mode) of drug administration. Presence of concomitant diseases (comorbidities).

Most commonly prescribed antihypertensive drug class and agents. Assessment of drug-related problems (DRPs).

Assessment of suspected adverse drug reactions (ADRs). Patient adherence to therapy. Patient knowledge regarding pharmacological and non-pharmacological therapy.

### *Data analysis*

Microsoft Excel was used to feed and maintain the research study data. The graphs and tables were plotted using Microsoft Excel.

### *Ethical considerations*

This study was approved by the Institutional Ethics Committee (IEC approval number: IEC/IIMS&R/2021/66). Written informed consent was obtained from all participants.

## RESULTS

### *Gender distribution*

Out of 100 patients, 47 (47.0%) were males and 53 (53.0%) were females. Gender distribution significantly impacts patient surveys, affecting response patterns, healthcare experiences and how results are interpreted (Figure 1).

### *Age distributions*

Antihypertensives were prescribed across various age groups, with the highest proportion of patients aged 51-60 years (36.0%), followed by those aged 41-50 years (17.0%), 71-80 years (15.0%), 61-70 years (13.0%), 31-40 years (10.0%), 81-90 years (7.0%) and 20-30 years (2.0%) (Figure 2).

### *Types of antihypertensives prescribed*

A total of 8 different types of antihypertensive drugs were prescribed across 100 prescriptions. In total, 126 drugs

were prescribed, with the most common being angiotensin ii receptor blockers (ARB) (42) (33.3%), Diuretics (37) (29.3%), calcium channel blockers (Ca<sup>+</sup> channel blockers) (15) (11.9%), vasodilators (13) (10.3%), beta blockers (13) (9.5%), alpha 2 antagonists (3) (2.3%), ACE inhibitors (3) (2.3%) and alpha 1 blockers (1) (0.7%) (Figure 3).

#### Mode of administration of drugs

The routes of administration of anti-hypertensive drugs were 88 (88.0 %) from the oral route and 12 (12.0%) from the IV route, respectively (Figure 4).

#### Co-morbid illness

The co-morbid condition was present in 52 (52.0%) patients and absent in 48 (48.0%) Figure 5.

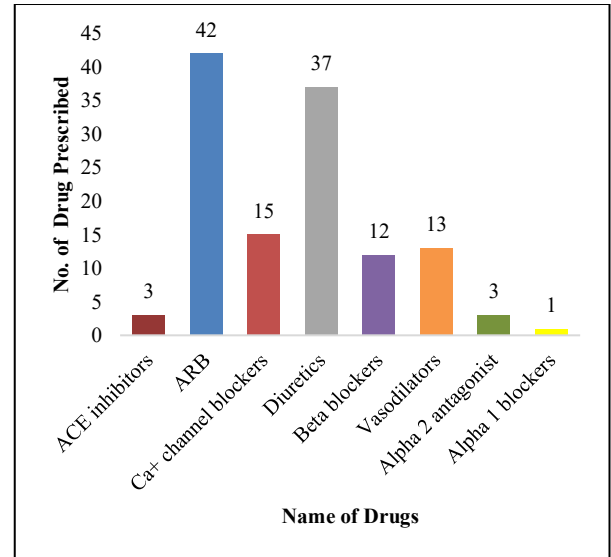


Figure 3: Types of antihypertensive drugs.

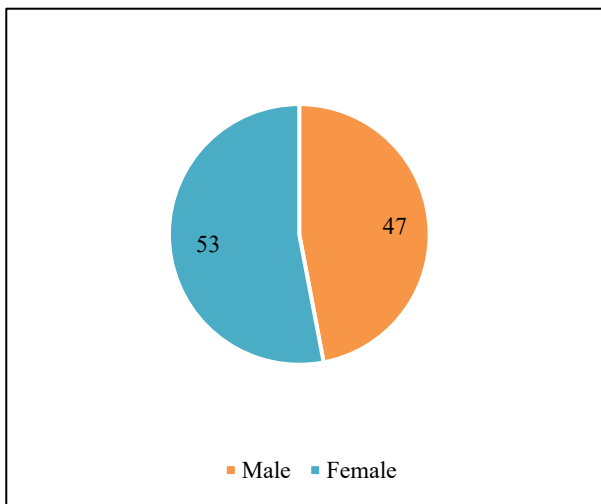


Figure 1: Gender distributions.

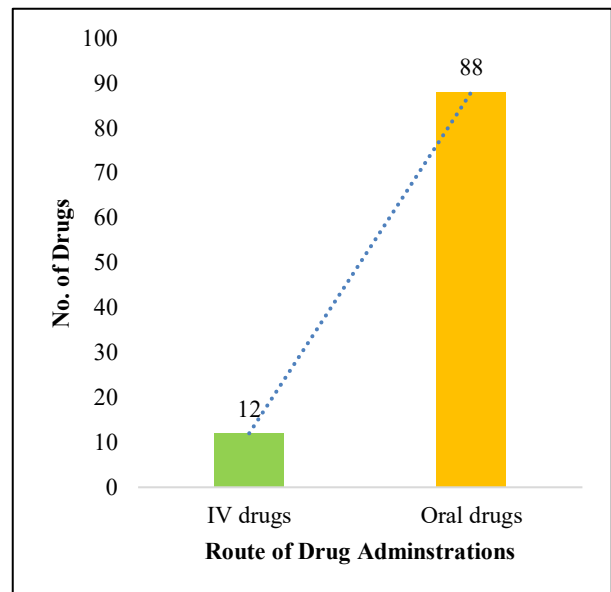


Figure 4: Route of administration of drugs.

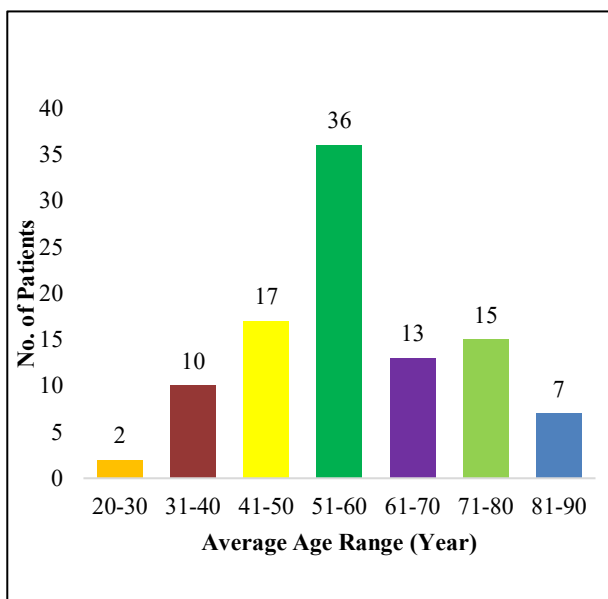


Figure 2: Average age range of patients utilizing antihypertensive drugs.

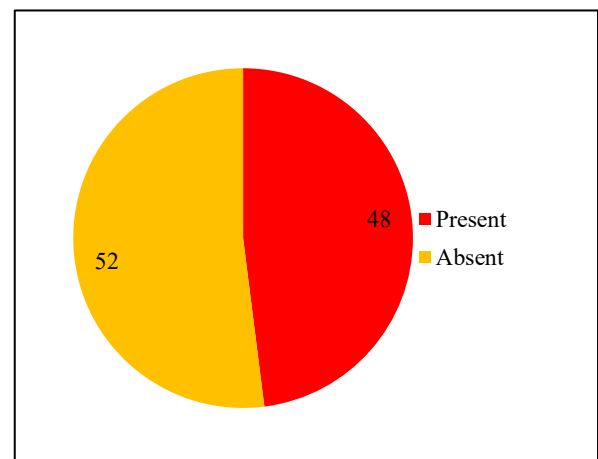
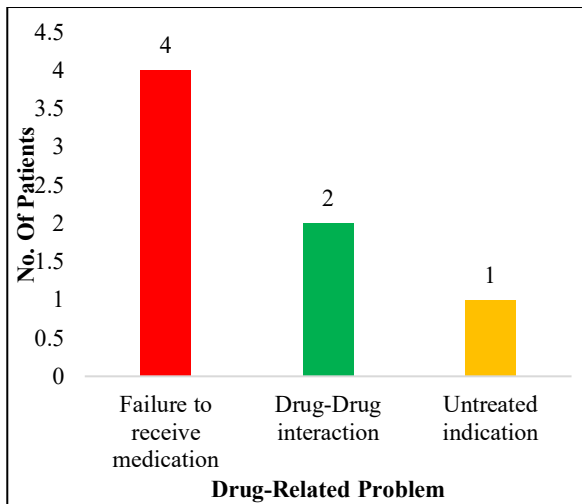


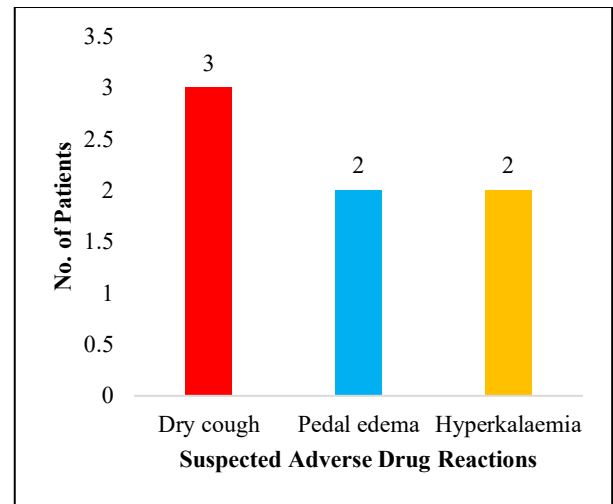
Figure 5: Co-morbid illness.



**Figure 6: Number of drug-related problems.**

#### *Average numbers of drug-related problems*

Most of the antihypertensives were prescribed to 100 patients. The drug-related problems found were failure to receive medication (4) (57.1%), drug-drug interaction 2 (28.6%) and untreated indication 1 (14.3%) (Figure 6).



**Figure 7: Analysis of suspected adverse drug reactions.**

#### *Analysis of suspected adverse drug reactions*

The highest ADRs identified from enalapril were dry cough 3 (42.9%), while amlodipine caused pedal edema 2 (28.6%) and telmisartan+spironolactone caused hyperkalaemia 2 (28.0%) 57%) (Table 1 and Figure 7).

**Table 1: Analysis of suspected adverse drug reactions.**

| Suspected ADRs | No. of patients | (%)   | Suspected drugs            | Severity |
|----------------|-----------------|-------|----------------------------|----------|
| Dry cough      | 3               | 42.90 | Enalapril                  | Possible |
| Pedal edema    | 2               | 28.60 | Amlodipine                 | Definite |
| Hyperkalaemia  | 2               | 28.60 | Telmisartan+spironolactone | Probable |
| Total          | 7               | 100   |                            |          |

## **DISCUSSION**

The clinical study, i.e., Assessment of adverse drug reactions & drug-related problems, is carried out in the inpatient and outpatient departments of Integral University Hospital, Lucknow. In the study, 100 patients were selected according to inclusion and exclusion criteria. Demographic characteristics showed that Females suffering from hypertension were more than Males in the study. It was observed that among them (male and female), 47 were male and 53 were female (Figure 1). Furthermore, it was found that most patients with hypertension were in the 50-60 years age group, while the lowest percentage was in the 20-30 years age group. (Figure 2).

However, hormonal changes after menopause, such as decreased estrogen levels and reduced activation of nitric oxide and prostacyclin, result in women over 65 having reduced vasodilatation activity. This can lead to a rise in blood pressure.<sup>9</sup> Alcoholism, smoking and tobacco chewing are also major problems in India, especially in villages. In the present study, the majority of male patients were alcoholics and smokers. Recent clinical and

epidemiological studies have confirmed that long-term ethanol consumption (more than three drinks per day, 30 g ethanol) is linked to an increased risk of cardiovascular diseases and a higher incidence of hypertension.<sup>10-15</sup> Heavy drinkers typically experience blood pressure rises of 5 to 10 mmHg, with systolic increases usually being higher than diastolic increases.<sup>16</sup>

Overall, 48 had co-morbidities in the study; among them, some had single co-morbidities, whereas a few had double or triple co-morbidities (Figure 5). In the study, 100 prescriptions were analyzed. According to the guideline, patients with Stage 2 hypertension must be treated with two medications at the same time, either a calcium channel blocker or a thiazide diuretic combined with an ARB or ACE inhibitor inhibitor.<sup>9</sup> A total of 126 antihypertensive drugs prescribed in this study, of which (33.3%) were ARB and (29.3%) were diuretics, (11.9%) were CCB, (10.3%) were vasodilators, (9.5%) were beta blockers, (2.3%) were ACE inhibitors and alpha 2 antagonists, (0.7%) were alpha 1 blockers (Figure 3). During the study, it was observed that the most commonly prescribed anti-hypertensive drug classes were angiotensin receptor blockers and diuretics.

The most commonly prescribed combination anti-hypertensive was telmisartan+amlodipine. The plasma concentration–time profiles of telmisartan in elderly subjects were similar to those in younger subjects and comparing the pharmacokinetic parameters of telmisartan in the elderly with those in younger subjects at the 20 and 120 mg doses showed no significant differences.

The findings also demonstrate that telmisartan did not accumulate significantly in older participants.<sup>17</sup> In our study, the routes of administration of anti-hypertensive drugs were oral (88.0%) and IV (12.0%), respectively (Figure 4). In the study, it was found that all the Antihypertensive drugs were prescribed by their brand names only. Based on the Naranjo scale, 03 ADRs were reported during the study: hyperkalemia was observed in 02 patients (28.6%), Pedal edema in 02 patients (28.6%) and dry cough in 03 patients (42.9%). Pedal edema was a side effect of amlodipine use in the study, similar to the study by Palikhey et al.<sup>18</sup> Dry cough was a side effect among enalapril users in the study, consistent with the findings of Woo et al.<sup>19</sup> The cough is mediated by the accumulation of bradykinin, substance P and/or prostaglandins in the lungs. Potassium-sparing diuretics can cause hyperkalemia. Diuretics promote the elimination of various electrolytes, which can cause hypo- or hyper effects.<sup>20</sup>

In the current study, hyperkalemia was the ADR observed in 02 patients (28.6%) (Figure 7 and Table 1). Overall, 3 drug-related problems were observed during the study; failure to receive medication was most common in 4 patients, whereas drug-drug interaction occurred in 2 patients and an untreated indication occurred in 1 patient. A study on DRP conducted in Malaysia also showed that the most common DRP was drug interactions (33.7%) with an antihypertensive and antiplatelet medication, mainly linked to DRPs in hypertensive patients with comorbidities (Figure 6).<sup>21</sup> All the patients admitted to the medicine department with Hypertension were treated with medications. Hence, lifestyle modifications such as exercise, low sodium intake, quitting smoking, reducing stress and following the DASH diet may be helpful.

## CONCLUSION

Furthermore, the reported ADRs were classified as possible according to Naranjo's probability scale. Therefore, patients on anti-hypertensive medications often experience adverse drug reactions. Our study recommends consistent ADR monitoring in hospital settings to ensure rational prescribing.

## ACKNOWLEDGMENTS

The authors would like to acknowledge the Department of Pharmacy Practice, Faculty of Pharmacy, Integral University, Lucknow, U.P. India for providing all the research facilities and manuscript communication number (IU/ R & D/2023-MCN0002099)

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee (Ref: IEC/IIMS&R/2021/66)*

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**Cite this article as:** Khan A, Tanveer A, Vohra A, Khan TA, Akhter MS, Goyal A, et al. A cross-sectional study on hospital-based evaluation of adverse drug reactions and drug-related issues in hypertensive patients. *Int J Basic Clin Pharmacol* 2026;15:996-1001.