



A Cross-Sectional Study on Hospital-Based Evaluation of Adverse Drug Reactions and Drug-Related Issues in Hypertensive Patients

¹Aqsa Khan, ¹Alhamd Tanveer, ¹Amisha Vohra, ¹Tooba Amin Khan, ¹Md Sohel Akhter*,

²Abhishek Goyal, ³Md Afroz Ahmad, ¹Md Nematullah

¹Department of Pharmacy Practice, Faculty of Pharmacy, Integral University, Lucknow, Uttar Pradesh, India-226026.

²Department of Medicine, Integral Institute of Medical Sciences and Research (IIMS&R), Integral University, Lucknow, Uttar Pradesh, India-226026.

³School of Pharmaceutical Education & Research, Jamia Hamdard University, Hamdard Nagar, New Delhi, India-110062.

Keywords

Adverse Drug Reaction,
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Abstract

Objective: 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. **Material and Methods:** This was a prospective, observational study. A total of 100 patients who met the inclusion and exclusion criteria were recruited from the general medicine division's outpatient and inpatient departments 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%). **Conclusion:** Patients taking anti-hypertensive medications frequently encounter adverse drug reactions. Our study recommends regular ADR monitoring in hospital settings to encourage rational medication prescribing.

*Corresponding Author:

Dr. Sohel Akhter (msakhter786s@gmail.com)

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1. Introduction

Drug-related problems are a major challenge for healthcare providers. It severely compromises management effectiveness, making this a crucial issue in population health from both the value-of-life and health-economics perspectives [1]. Problems related to

drugs that occur among hypertensive patients could delay or prevent patients from achieving their desired therapeutic goals. It has been ascribed to needless over-prescription of medication, considerable deterioration of diseases, unnecessary increases in

hospital admittance rates, and longer hospital stays, leading to a major medical load. As a consequence, considerable numbers of patients do not receive the full benefits of health care, resulting in poorer health outcomes, lower quality of life, increased health care expenses, and eroding public confidence in health systems [2],[3],[4].

Therefore, the objective of the present study was to determine the pattern and magnitude of drug-related problems in the study hospital and to identify risk factors for these problems. Hypertension is defined as persistent elevated blood pressure, with systolic and diastolic blood pressure at or above 140/90 mmHg. Hypertension is a significant global public-well-being challenge because of its high prevalence and its role as a risk factor for cerebrovascular, cardiovascular, and renal diseases [4], [5],[6]. It is a silent killer disease in both developed and developing nations of the world. It is an essential global public-wellbeing challenge because of its elevated frequency and hazard factor for cerebrovascular, cardiovascular, and renal disease [7], [8]. Adverse Drug Reactions related to medications are common and inflict a severe health-associated problem, which can limit the management options, obedience, and even lead to discontinuation of treatment [9]. Hypertension is a long-term disease situation that is considered to be one of the most important cardiovascular risk factors [10]. For the management of hypertension, a broad choice of anti-hypertensive agents exists as single or combination treatment to attain a target blood pressure in individual patients.

In contrast, the combination treatment increases the threat of initiating an Adverse Drug Reaction. Patients with hypertension frequently have concurrent medical conditions such as hyperlipidaemia, impaired glucose metabolism, and renal impairment, leading to an increased rate of cardiovascular morbidity and mortality [11],[12],[13],[14]. The World Health Organization (WHO) has estimated that about 62.0% of cerebrovascular disease and 49.0% of ischemic heart disease burden worldwide are attributable to suboptimal control of blood pressure levels [15],[16],[17],[18]. High blood pressure is estimated to cause 7.1 million deaths annually, accounting for 13.0% of all deaths globally [19],[20],[21]. The primary objective of the study was to assess the adverse drug reactions & drug related problems in patients with hypertension at a tertiary care hospital, Lucknow. The secondary objective of the study was to evaluate the treatment pattern and outcome of patients with hypertension at a tertiary care hospital, Lucknow

2. Material and Methods

A prospective, cross-sectional, non-experimental (observational) study was conducted across various inpatient (IPD) and outpatient (OPD) departments at the Integral Institute of Medical Sciences and Research (IIMS&R), Lucknow, India, over 6 months (Nov. 2021-May 2022). During our 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. Diagnosis, patient complaints, number of drugs prescribed, social history, generic name, and brand name were recorded using the daily patient data collection form.

2.1 Inclusion Criteria

1. Hypertensive patients with written informed consent.
2. All patients aged 18 years or older.
3. Participants taking anti-hypertensive treatment for at least one month with regular OPD follow-up.
4. No Gender bias.
5. Pregnant and lactating patients were also included.
6. All patients with hypertension with other co-morbidities were also included.

2.2 Exclusion Criteria

1. Patients who had not started anti-hypertensive.
2. Patients who could not respond.
3. The interviewed and unconscious patients.
4. mentally unstable hypertensive patients.
5. Drug-abusing patients were excluded from this study.

2.3 Parameters Assessed

The following parameters were evaluated

1. Types of antihypertensive drugs prescribed.
2. Average number of antihypertensive drugs per prescription.
3. Route (mode) of drug administration.
4. Presence of concomitant diseases (comorbidities). Most commonly prescribed antihypertensive drug class and agents.
5. Assessment of drug-related problems (DRPs). Assessment of suspected adverse drug reactions (ADRs).
6. Patient adherence to therapy.
7. Patient knowledge regarding pharmacological and non-pharmacological therapy.

2.4 Data Analysis

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

3. Results

3.1 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).

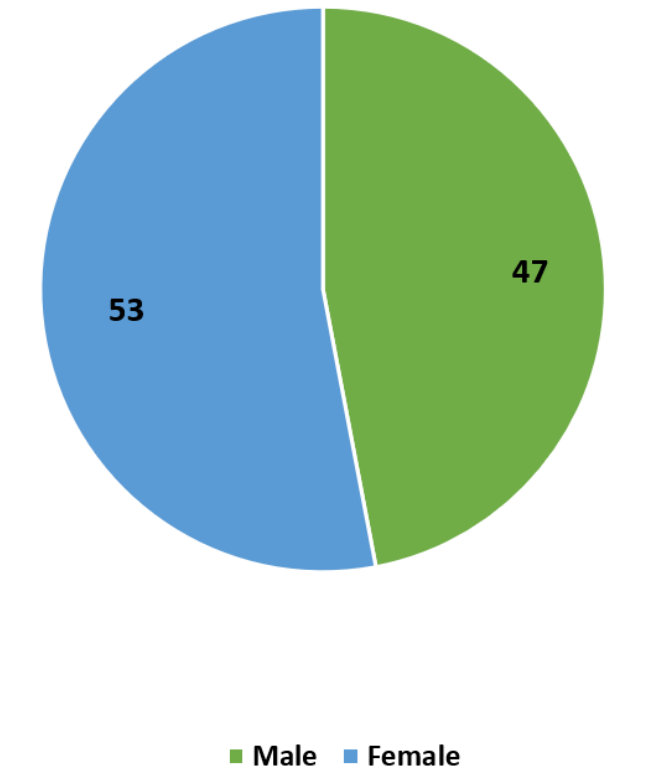


Figure 1: Gender distributions.

3.2 Age Distributions

Antihypertensive 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).

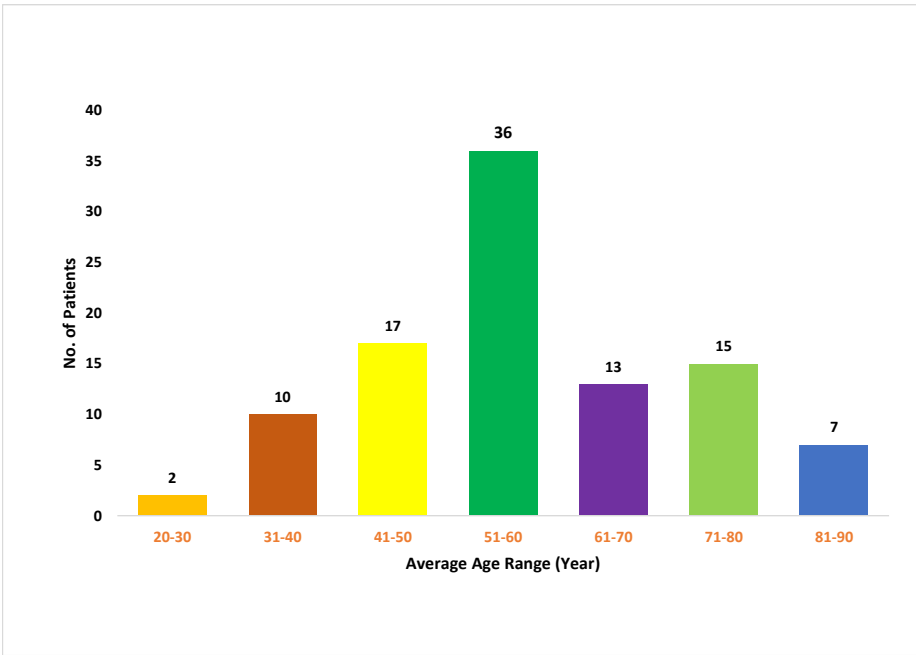


Figure 2: Average age range of patients utilizing antihypertensive drugs.

3.3 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⁺ channel blockers) (15) (11.9%), Vasodilators (13) (10.3%), Beta Blockers (12) (9.5%), Alpha 2 antagonists (3) (2.3%), ACE Inhibitors (3) (2.3%), and Alpha 1 Blockers (1) (0.7%) (Figure 3).

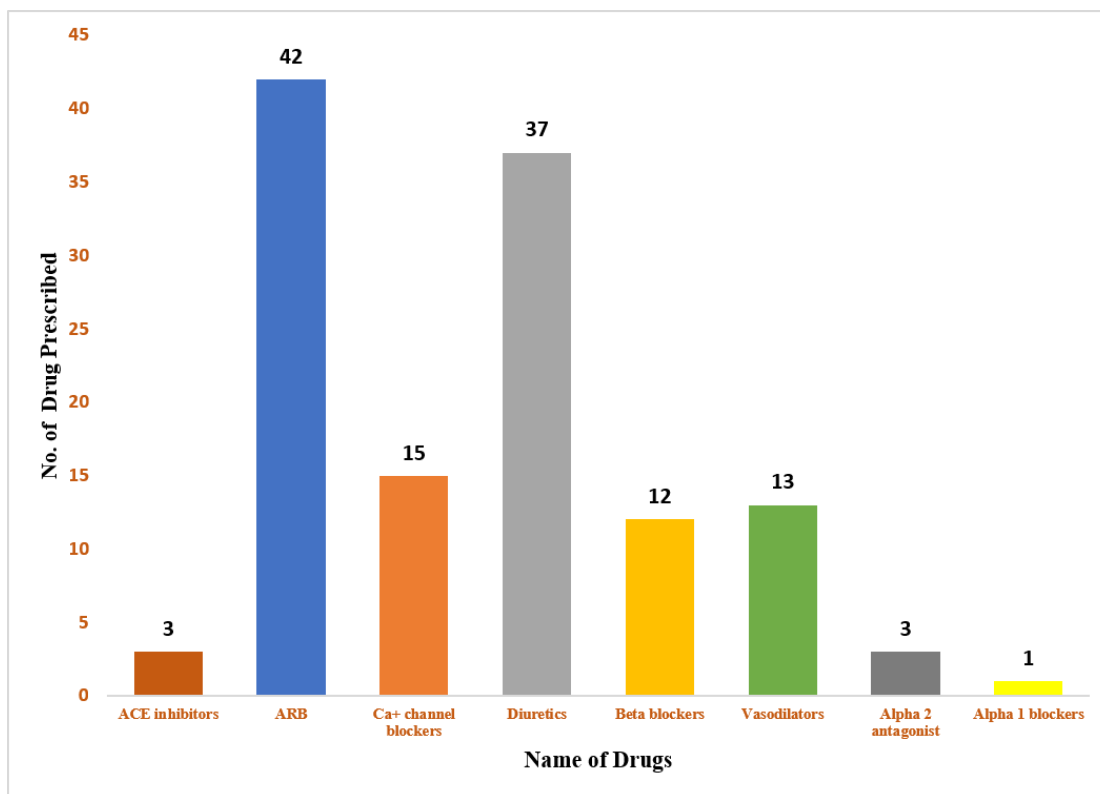


Figure 3: Types of antihypertensive drugs.

3.4 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).

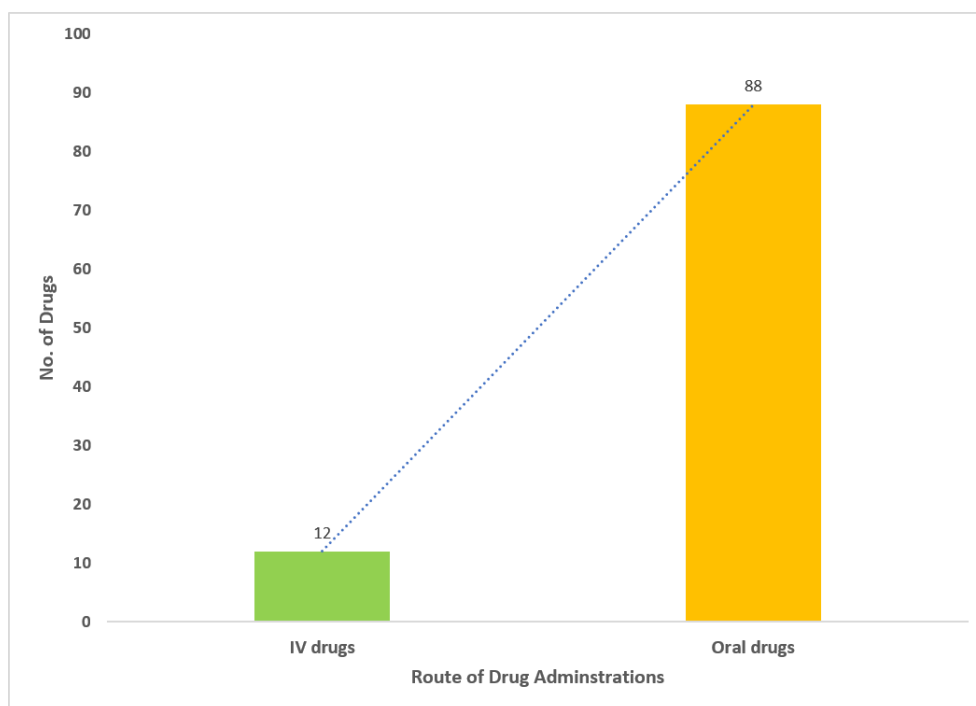


Figure 4: Route of administration of drugs.

3.5 Co-Morbid Illness

The co-morbid condition was present in 52 (52.0%)

patients and absent in 48 (48.0%).

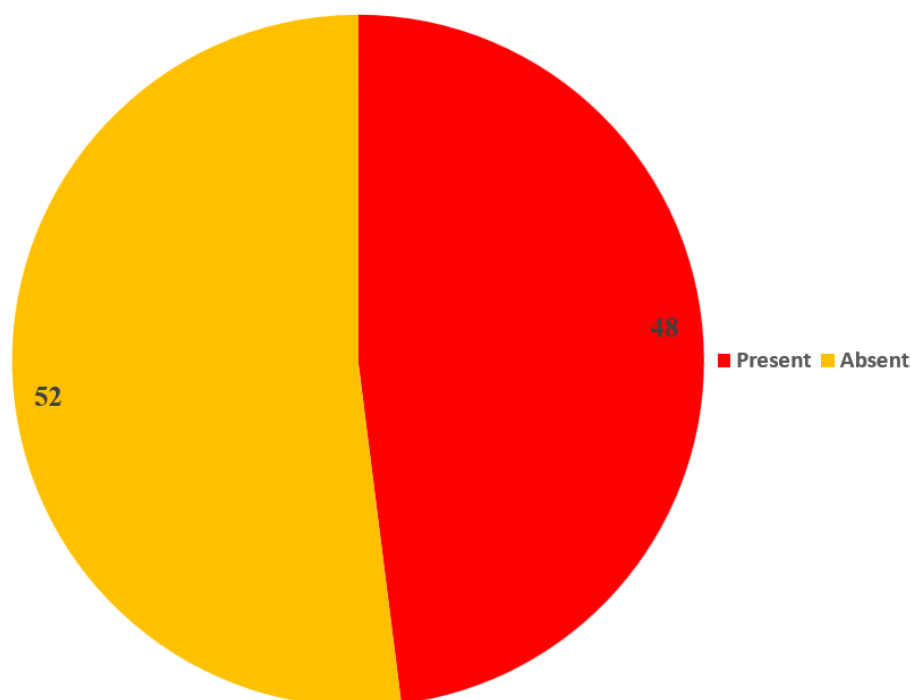


Figure 5: Most common anti- hypertensive prescribed.

3.6 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).

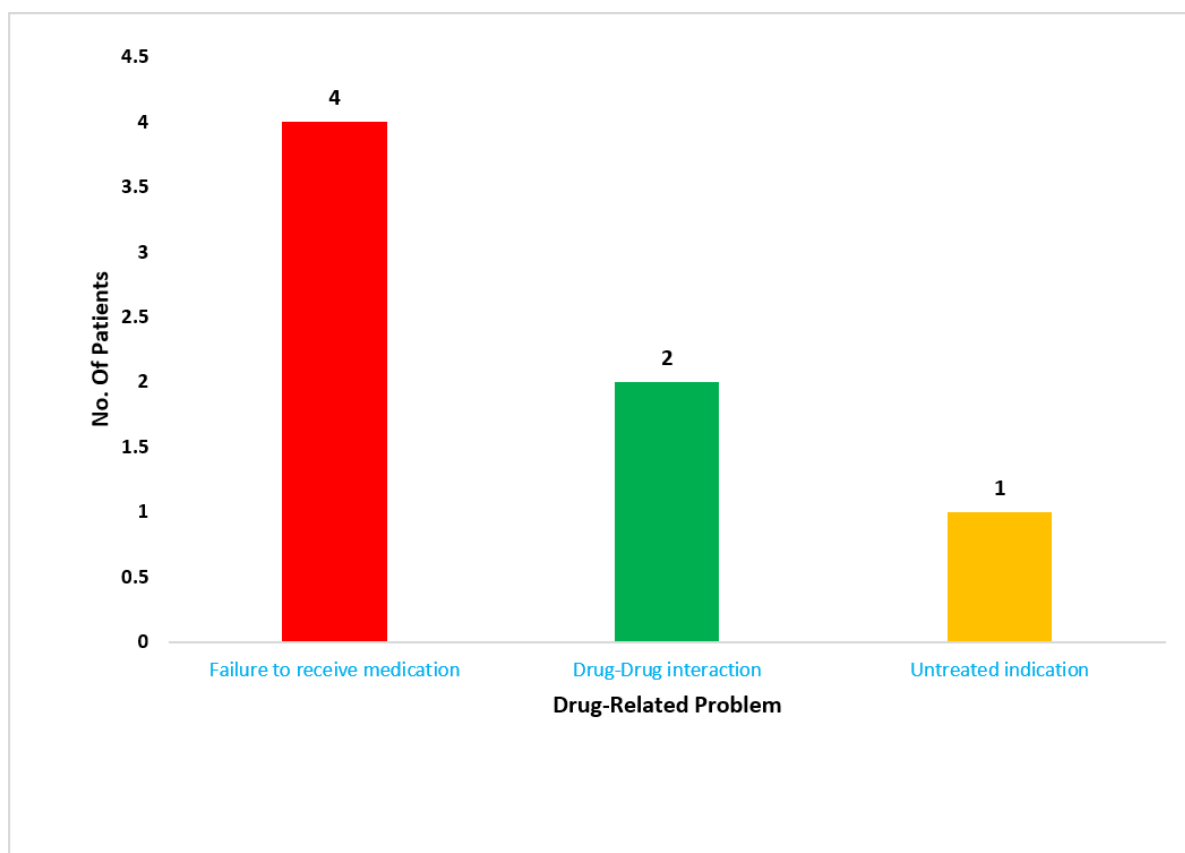


Figure 6: Number of drug-related problems.

3.7 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	Percentage (%)	Suspected Drugs	Severity
Dry cough	03	42.9%	Enalapril	Possible
Pedal edema	02	28.6%	Amlodipine	Definite
Hyperkalaemia	02	28.6%	Telmisartan + spironolactone	Probable
Total	07	100%		

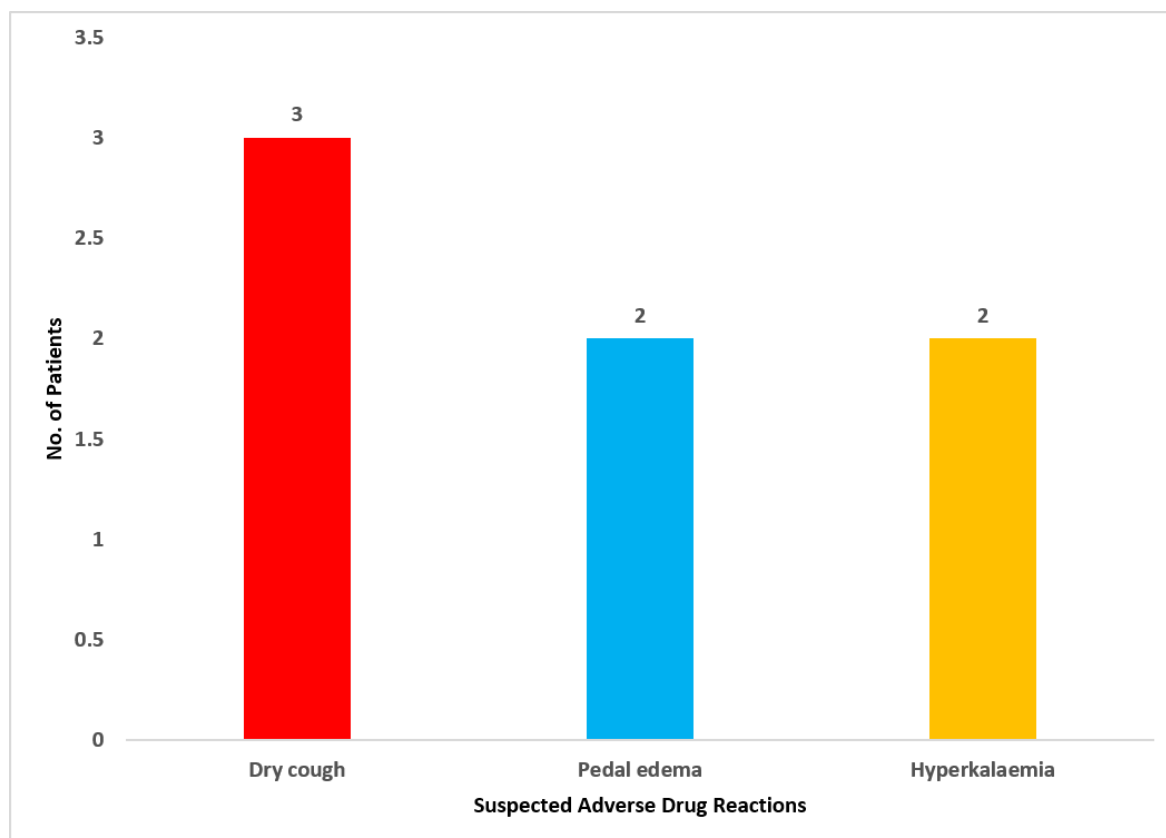


Figure 7: Analysis of suspected adverse drug reactions.

4. 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 our study, 100 patients were selected according to inclusion and exclusion criteria. Demographic characteristics showed that Females suffering from hypertension were more than Males in our study. It was observed that among them (male and female), 47 were male and 53 were female (Figure 1). Further, it was found that the majority of patients with Hypertension were in the 50-60 years age group, and the lowest % was in the 20-30 years age group (Figure 2). However, hormonal

changes after menopause, such as decreased estrogens and decreased activation of nitric oxide and prostacyclin, result in women over 65 having reduced vasodilatation activity. This can lead to a rise in blood pressure. 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 verified that long-term ethanol consumption (more than three drinks per day, 30 g ethanol) is associated with an increased risk of cardiovascular diseases and an increased incidence of hypertension. Heavy

drinkers usually experience blood pressure increases of 5 to 10 mmHg, with systolic increases almost always being greater than diastolic increases. Overall, 48 co-morbidities were observed in our study; some had single co-morbidities, whereas a few had double or triple co-morbidities (Figure 5).

In our study, 100 prescriptions were analyzed. According to the guideline, patients with Stage 2 hypertension must be treated with two medications simultaneously, either a calcium or thiazide antagonist combined with an ARB or ACE inhibitor. 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 our 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 observed in younger subjects, and comparison of 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. In our study, the routes of administration of anti-hypertensive drugs were oral (88.0%) and IV (12.0%), respectively (Figure 4).

In our 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 our study. Dry cough was a side effect of enalapril use in our study, consistent with the findings of investigations. The cough is mediated by 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. 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 about DRP done in Malaysia also showed that the most frequent DRP was drug interactions (33.7%) with an antihypertensive and antiplatelet agent that was mostly associated with DRPs in hypertensive patients with comorbidity (Figure 6). 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

Moreover, the reported ADRs were categorized as possible on Naranjo's probability scale. Hence, patients taking anti-hypertensive drugs commonly experience adverse drug reactions. Our study recommends regular ADR monitoring in hospital settings to support rational prescribing.

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Conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this paper.

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Ethics approval and consent to participate

The study received approval from the Institutional Ethics Committee (IEC), IIMS&R, with approval number: IEC/IIMS&R/2021/66.

Author Contributions

AK: Data Collection & Writing the manuscript; **AT:** Data Collection & Formatting; **AV:** Data Collection & Editing; **TAK:** Data Collection & Prepared Table & Graph; **MSA:** Conceptualization; **AG:** Clinical supervision; **MAA:** Software; **MN:** Resources.

Informed consent statement

Informed consent statements were explained to each patient, and the patients completed all responses.

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