



**INTERNATIONAL JOURNAL OF  
PHARMACEUTICAL SCIENCES**  
[ISSN: 0975-4725; CODEN(USA): IJPS00]  
Journal Homepage: <https://www.ijpsjournal.com>



## Review Paper

# A Pharmacovigilance Study of Antihypertensive Drugs with Reference to ADR Reporting and Patient Awareness in Hypertension

Sakshi Jadhav\*, Dhanashri Mali, Gauri Chaudhari, Sakshi Dawange, Vaishali Rawal, Dr. M. R. N. Shaikh

*MET's Institute of D Pharmacy, Bhujbal Knowledge City, Adgaon, Nashik, India.*

## ARTICLE INFO

Published: 01 June 2026

### Keywords:

Pharmacovigilance, ADR, Antihypertensive agent, Telmisartan

### DOI:

10.5281/zenodo.20486646

## ABSTRACT

The present study was conducted to evaluate adverse drug reactions (ADRs) associated with antihypertensive drugs and to assess the level of awareness and reporting practices related to pharmacovigilance among pharmacists and patients in the management of Hypertension. The study was designed as an observational, cross-sectional survey using structured questionnaires developed through Google Forms. A total of 100 responses were collected, including 50 pharmacists and 50 patients. The results indicated that telmisartan was the most commonly dispensed antihypertensive drug. A significant proportion of patients reported experiencing side effects; however, the majority did not report these reactions. Although pharmacists were found to be aware of pharmacovigilance and actively involved in patient counseling, patient awareness regarding ADR reporting systems was observed to be low. The findings of the study highlight a clear gap between the occurrence and reporting of adverse drug reactions, primarily due to lack of awareness. This study emphasizes the need to improve patient education and strengthen pharmacovigilance practices to ensure drug safety and enhance therapeutic outcomes.

## INTRODUCTION

### ◆ Concept of Pharmacovigilance:

#### ❖ Definition:

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects

or any other drug-related problems, is intrinsically linked to effective information management.

#### ❖ Objectives:

1. Monitoring Adverse Effects
2. Assessment Of Risk and Benefits
3. Data Collection and Analysis

\*Corresponding Author: Sakshi Jadhav

Address: MET's Institute of D Pharmacy, Bhujbal Knowledge City, Adgaon, Nashik, India..

Email ✉: [sakshijadhavrj@gmail.com](mailto:sakshijadhavrj@gmail.com)

**Relevant conflicts of interest/financial disclosures:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



4. Risk Management and Mitigation
5. Promoting Safe Use of Medications
6. Communication and Information Dissemination
7. Regulatory Compliance: Post Marketing surveillance

#### ❖ **Primary Types of Pharmacovigilance Methods**

- **Spontaneous (Passive) Reporting:** The basis for signal identification is the voluntary reporting of unfavourable events by patients or healthcare providers.
- **Active Surveillance:** Proactively gathering information on adverse drug reactions (ADRs) via patient registries, cohort studies, or close observation of particular drugs.
- **Targeted Clinical Investigations:** Particular research projects intended to investigate known or suspected safety hazards for a certain medication.
- **Drug usage/Misuse Monitoring:** Concentrated observation of negative consequences associated with medication usage or misuse.

#### ❖ **Components of PV System:**

1. Data Collection
2. Spontaneous Reporting
3. Active Surveillance System
4. Signal Detection and Management.

#### ❖ **Pharmacovigilance Awareness:**

Pharmacovigilance is the science and practice of identifying, evaluating, comprehending, and preventing adverse drug reactions (ADR). Underreporting is India's pharmacovigilance program's main problem. The primary cause is a lack of awareness, information, attitude, and practice among medical practitioners. This study's primary goal was to evaluate second professional MBBS students' knowledge, attitudes, and

behaviours about reporting adverse drug reactions (ADRs) and to give them a pharmacovigilance workshop as an intervention to raise their awareness because they will soon be practicing physicians.

#### ❖ **Key Objectives of Pharmacovigilance:**

1. Monitoring drug safety in real-world settings.
2. Identifying previously unrecognized ADRs.
3. Assessing benefit-risk profiles throughout the drug lifecycle.
4. Promoting safe and rational drug use.
5. Supporting regulatory decision-making, including label updates or withdrawals.

#### ❖ **Definition Of ADR:**

World Health Organization (WHO) defines that adverse drug reactions (ADRs) are noxious and unwanted effects produced by the drug, when it is applied for the ailment of disease or diagnosis

#### ❖ **Benefits of ADR Monitoring:**

1. It provides information about the safety and quality of medicinal items.
2. Risk-management strategies are started.
3. It helps measure the occurrence of ADRs and avoids the predictable negative effects.
4. It raises awareness of adverse drug reactions (ADRs) and educates patients, nurses, pharmacists, and the medical staff about them.

#### ❖ **Classification Of Adverse Drug Reaction:**

1. **Type-A:** Augmented
2. **Type-B:** Bizarre
3. **Type-C:** Continuous drug use
4. **Type-D:** Delayed
5. **Type-E:** End of dose
6. **Type-F:** Failure of therapy.

#### ❖ **Clinical Research:**

##### ➤ **Definition of clinical trials:**



A clinical trial is a systematic process that is intended to find out the safety and efficacy of a drug, device in treating, preventing, diagnosing a disease or a medical condition performed on human participants in clinical research.

❖ **Phases Of Clinical Trials:**

1. Phase I: Safety and Dosage
2. Phase II: Efficacy and Side Effects
3. Phase III: Large-Scale Testing
4. Phase IV: Post-Marketing Surveillance Phase

❖ **GOOD CLINICAL PRACTICE:**

➤ **Good clinical practice:**

- The most crucial factors are the trial subjects' rights, safety, and welfare, which should take precedence over the interests of society and research. An investigational product should have sufficient nonclinical and clinical data to justify the planned clinical trial.
- Clinical trials should have a clear, comprehensive procedure and be grounded in science. A protocol that has already been approved by the institutional review board (IRB) or the independent ethics commission (IEC) or acquired a favourable opinion should be followed when conducting a trial.

❖ **Scope Of ICH:**

➤ **Good clinical Practice:** This guideline is applicable to interventional clinical trials of investigational products<sup>1</sup> that are meant to be submitted to regulatory bodies. In compliance with local regulations, this guideline may also apply to other interventional clinical trials of investigational drugs that are not meant to support applications for marketing authorization.

➤ **Protocol Designing for Clinical Trials:**

Any clinical protocol must have the right "building blocks" in order to be successful. These "building blocks" include fundamental elements including participant recruitment, information technology and systems, financial dynamics, ethics and regulatory compliance, people-management abilities, scientific technique, and institutional commitment.

➤ **Process Of Clinical Trial Application:**

Clinical trials on pharmaceuticals must be authorized by the CSC committee based on a favourable decision by the local IRB, as per Article 10 of the CSL. An outline of the process for submitting and reviewing the CTA at JFDA is given in Figure 2. According to Section 8 of the ICH-GCP guidelines, the CTA dossier must contain the necessary papers. The numerous legalizations and notarizations needed for the documents—particularly those produced outside, which is a pretty typical procedure in MENA—are a significant burden. A human research subject cannot take part in more than one BA/BE study within 80 days and must be between the ages of 18 and 50.

❖ **AMC Centres:**

Regional Adverse Drug Reaction Monitoring Centres (AMCs) are strategically placed throughout the nation to enable effective data collecting and analysis. By processing ADR reports and sending pertinent data to the NCC, these AMCs serve as regional hubs. Healthcare professionals and the general public will find the reporting mechanism easy to use as it is designed to be available to several stakeholders, including an online portal created by the CDSCO.

STATES	AMC CENTERS
Delhi	All India Institute of Medical Sciences
Maharashtra	KEM Hospital



Maharashtra	BJ Government Medical College
Gujrat	BJ Medical College
Karnataka	St. John's Medical College
Tamil Nadu	Madras Medical College
Uttar Pradesh	King George's Medical University
Telangana	Osmania Medical College
West Bengal	Medical College, Kolkata

❖ **Overview of Hypertension:**

- Hypertension, defined as an increase in systolic blood pressure, diastolic blood pressure, or both above normal ranges, is widespread in both industrialised and developing countries, and its prevalence rises with age.

- High blood pressure is also known as hypertension. It can cause serious health problems and increase the risk of heart disease, stroke, and even death

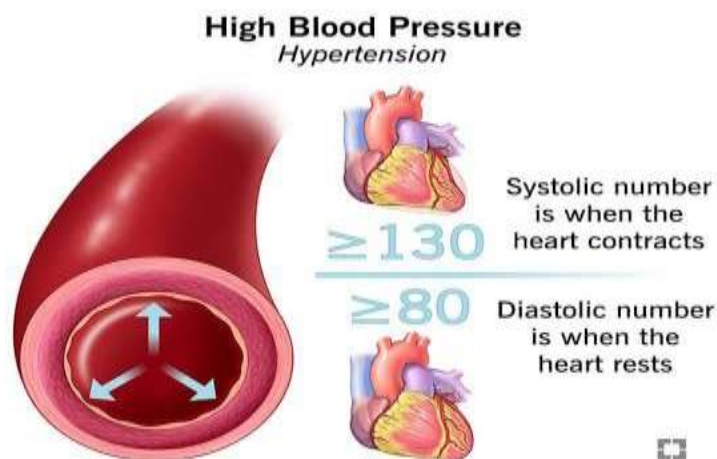


Figure No:1

Table No :1

Blood Pressure Stages		
Category	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)
Normal	<120	< 80
Pre hypertension	120-139	80-89
Hypertension (stage 1)	140-159	90-99
Hypertension (stage 2)	≥ 160	≥100
Hypertension (stage 3)	>180	>110

❖ **Sphygmomanometer:**

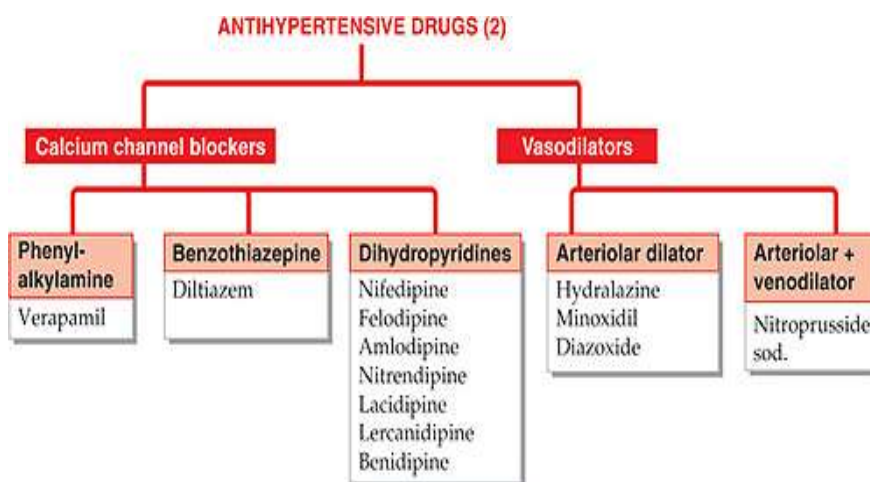
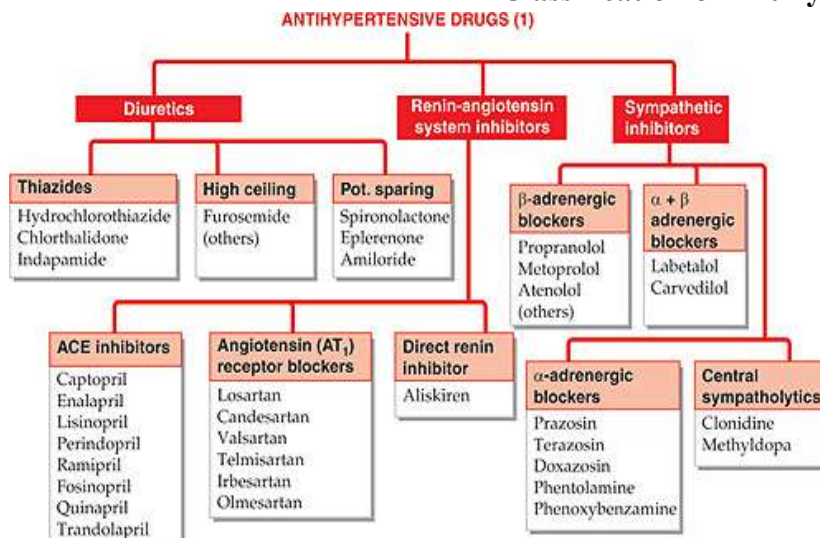
A mercury sphygmomanometer is the common device used to monitor blood pressure. Mercury, which has long filled the middle column of traditional sphygmomanometers, is measured in units of mercury.

❖ **Antihypertensive Agents:**

Antihypertensive drugs are medicines used to treat high blood pressure (hypertension). They help lower blood pressure and reduce the risk of complications like heart attack, stroke, and kidney disease.

❖ Pharmacological Treatment

• Classification of Antihypertensive Drugs

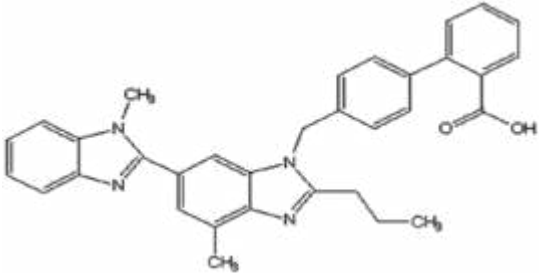


• Non-Pharmacological Treatment

1. Regular Physical Exercise
2. Stress Reduction

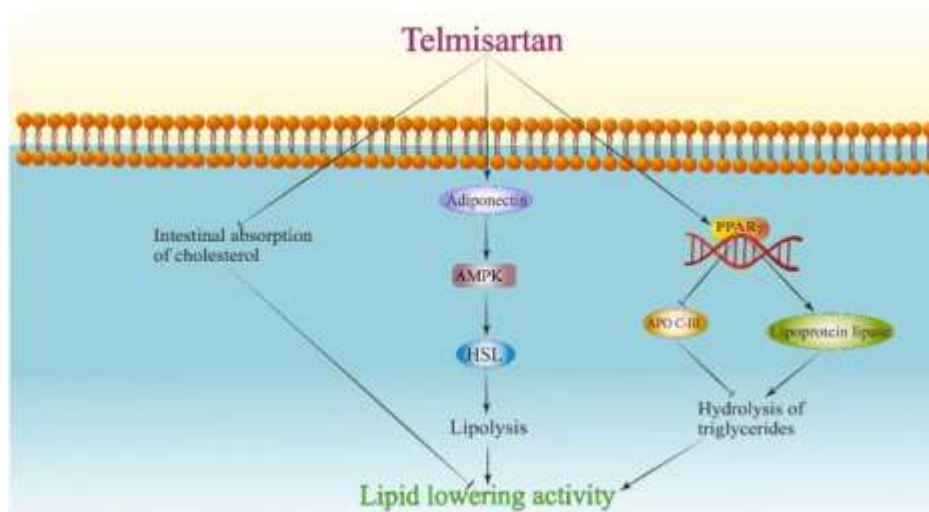
❖ Telmisartan Drug Profile:

Table No:2

Name	Telmisartan
Chemical Name	2-(4-{[4-methyl-6-(1-methyl-1H-1,3-benzodiazol-2-yl)-2-propyl-1H-1,3-benzodiazol-1-yl]methyl}phenyl)benzoic acid.
Molecular Formula	C33H30N4O2
Structure	

<b>Molecular Weight</b>	514.62 gm/mol
<b>Description</b>	A white to off - white crystalline powder
<b>Dose</b>	40 mg once a day
<b>Melting Point</b>	261-263°C
<b>Boiling Point</b>	771.9°C
<b>Category/ Therapeutic Class</b>	Antihypertensive
<b>Solubility</b>	Sparingly soluble in dichloromethane, slightly soluble in methanol, practically insoluble in water.
<b>Pharmacological Action</b>	selectively binding to AT1 receptors, preventing vasoconstriction and aldosterone-induced sodium/water retention.

- Many people believe that the tolerability profiles of angiotensin II receptor blockers (ARBs), which are very effective antihypertensive drugs, are comparable to those of placebos. With a half-life of roughly 24 hours, telmisartan has the longest of all the commercially marketed ARBs. This implies that telmisartan should have a prolonged duration of action, guaranteeing blood pressure regulation during the once-daily dosage interval.
- One such characteristic that sets telmisartan apart from other ARBs is its high lipophilicity. This improves intracellular absorption, tissue penetration, and bioavailability. The huge distribution volume of about 500L is indicative of the high lipophilicity. As shown in an animal model, telmisartan's greater lipophilicity than losartan may provide vascular protection.



## CH-2: LITERATURE STUDY

### ❖ Telmisartan clinical trials:

1. Identification of telmisartan as a unique angiotensin II receptor antagonist with selective PPAR- $\gamma$ -modulating activity
2. Angiotensin type 1 receptor blockers induce peroxisome proliferator activated receptor activity
3. An angiotensin II AT1 receptor antagonist, telmisartan augments glucose uptake and GLUT4 protein expression in 3T3-L1 adipocytes

4. Telmisartan is a dual ARB and PPAR gamma activator that limits weight gain, body fat accumulation, and adipocyte size in rats fed a high fat, high carbohydrate diets
5. Insulin-sensitizing effects of telmisartan: Implications for treating insulin-resistant hypertension and cardiovascular disease.

Long-term treatment is necessary for hypertension. Antihypertensive medications, however, may result in adverse drug reactions (ADRs) that compromise quality of life and compliance. 500 patients taking at least one antihypertensive drug participated in this 12-month prospective observational trial. Pedal

edema, dry cough, and dizziness were the most common adverse drug reactions (ADRs) among the 95 ADRs (17.6%), which were mostly caused by calcium channel blockers and ACE inhibitors. Patients on polypharmacy had considerably more adverse drug reactions (ADRs) ( $p = 0.004$ ), with the majority being categorized as moderate and likely. To enhance safety and maximize the management of hypertension, active pharmacovigilance is crucial.

❖ **Major Clinical Outcomes Comparing Telmisartan and other ARBs**

Events	Total number for analysis	5-year cumulative rate (%)
<b>Heart Failure</b>		
Other ARBs	41,598	801 (1.926%)
Telmisartan	41,598	540 (1.298%)
<b>Stroke</b>		
Other ARBs	40,026	1,868 (4.667%)
Telmisartan	40,219	1,383 (3.439%)
<b>Coronary Artery Disease</b>		
Other ARBs	36,331	3,924 (10.801%)
Telmisartan	36,376	3,529 (9.701%)
<b>All cause Death</b>		
Other ARBs	41,538	1,529 (3.681%)
Telmisartan	41,524	810 (1.951%)

In this extensive, real-world cohort study that made use of the TriNetX Global Collaborative Network, we assessed cardiovascular outcomes in almost 1.9 million hypertension patients and found 41,598 individuals who were well-matched for each therapy group. When compared to other ARBs, telmisartan use was continuously associated with lower risks of heart failure, stroke, and all-cause mortality. These results, which were seen in important clinical subgroups, imply that telmisartan may provide additional cardiovascular and cerebrovascular advantages over blood

pressure management. Our findings support telmisartan as a potentially beneficial treatment choice for hypertension patients at elevated cardiovascular risk, even though additional prospective studies are required to demonstrate causality.

❖ **ADRs of Antihypertensive Drugs:**

- **Angiotensin Receptor Blockers and The ADRs observed**

ADRs	No. of ADR (%)	Drug	Individual No.
Hypotension	7 (36.84)	Losartan	3
		Telmisartan	2
		Olmesartan	2
Dry Cough	3 (15.78)	Losartan	3



Weakness	3 (15.78)	Losartan	2
		Telmisartan	1
Hyperkalemia	2 (10.52)	Losartan	2
Myalgia	2 (10.52)	Losartan	2
Headache	2 (10.52)	Losartan	2
Total	19 (100)		19

### CH-3 NEED OF STUDY AND OBJECTIVE

#### 1. High Hypertension Prevalence

One of the most prevalent chronic illnesses in the world, hypertension affects a significant percentage of adults. Because to sedentary lifestyles, stress, obesity, poor diets, smoking, and alcohol consumption, the number of individuals with hypertension is steadily rising.

#### 2. Serious Public Health Issue

Because it is a major risk factor for major cardiovascular problems such stroke, myocardial infarction, renal problems, and heart failure, hypertension is regarded as a major public health concern. Increased morbidity and mortality can result from uncontrolled blood pressure.

#### 3. Growing Patient Population

Due to urbanization, population aging, inactivity, and dietary changes, the incidence and prevalence of hypertension are rising both worldwide and in India.

#### 4. The Requirement for Extended Therapy

Antihypertensive medications are typically needed to treat hypertension for the rest of one's life. Long-term and continuous medication therapy raises the risk of drug interactions, adverse drug responses, and problems with patient compliance.

#### 5. The Value of Tracking Adverse Drug Reactions

Despite their effectiveness, antihypertensive drugs have a number of adverse drug reactions (ADRs), including headache, dizziness, hypotension, exhaustion, and edema.

6. To guarantee patient safety, increase treatment compliance, and improve therapeutic results, it is critical to monitor these reactions.

#### 7. Widespread Amlodipine Use

Amlodipine's efficacy and easy once-daily dosage make it one of the most often recommended hypertension medications. However, it is crucial for pharmacovigilance evaluation because it is often linked to adverse drug reactions (ADRs) such peripheral edema, flushing, dizziness, and palpitations.

#### 8. Lack of ADR Reporting Awareness

There is inadequate awareness among healthcare professionals and patients regarding ADR reporting and pharmacovigilance practices. Underreporting of ADRs remains a major challenge in ensuring medication safety.

#### 9. Importance of Pharmacovigilance

Pharmacovigilance helps in the detection, assessment, prevention, and reporting of adverse drug reactions. Conducting studies on hypertension can contribute to improving pharmacovigilance systems and promoting rational use of medicines.

#### 10. Common Symptoms of Hypertension

Many patients with hypertension remain asymptomatic; however, some may experience symptoms such as:

- Headache
- Dizziness
- Fatigue
- Blurred vision
- Chest pain
- Shortness of breath
- Palpitations
- Nosebleeds

### ❖ Objectives of the Study

- General Objective
1. To evaluate adverse drug reactions associated with antihypertensive drugs with special reference to amlodipine and to assess pharmacovigilance practices among patients and healthcare professionals.
- Specific Objectives
1. To study the pattern and frequency of adverse drug reactions associated with antihypertensive drugs.
  2. To identify and evaluate adverse drug reactions specifically associated with amlodipine.
  3. To assess the awareness and knowledge of pharmacovigilance among healthcare professionals.
  4. To evaluate the occurrence and reporting of adverse drug reactions among patients receiving antihypertensive therapy.
  5. To analyze adverse drug reactions using standard assessment tools such as the Naranjo ADR Probability Scale.

## CH-4 MATERIALS AND METHODS

### ❖ Study Design

In order to assess the adverse drug reactions (ADRs) linked to antihypertensive medications in actual clinical practice, the current study was planned as an observational, cross-sectional pharmacovigilance study. Particularly in chronic illnesses like hypertension where long-term drug usage is widespread, pharmacovigilance is essential to assuring drug safety after marketing. This study used a survey-based methodology, using structured questions created with Google Forms to gather information from patients and healthcare professionals. In addition to identifying frequently prescribed antihypertensive

medications, the study sought to evaluate the frequency, type, and reporting of adverse drug reactions (ADRs) linked to these treatments.

Based on replies received during the survey, common medications like telmisartan and other antihypertensive classes were given particular attention. The design made data entry simple.

### ❖ Study Population

Patients and healthcare professionals made up the two main segments of the study population. Pharmacists made up the majority of healthcare professionals, and they were selected as the key responders because of their accessibility and direct involvement in patient interactions and medicine distribution. Pharmacists are an essential source of pharmacovigilance data since they are crucial in identifying and reporting adverse drug reactions. Patients with a diagnosis of hypertension who were receiving antihypertensive medication were included in the second group. Real-world information about medication use, adverse effects, and treatment compliance was given by these patients. In order to ensure practical exposure and accurate data collection, the study was carried out in and around local regions, including community pharmacies and hospital settings.

### ❖ Inclusion Criteria

- Patients diagnosed with hypertension and currently receiving antihypertensive drug therapy.
- Healthcare professionals, especially pharmacists, involved in dispensing or monitoring medications.
- Participants willing to provide informed responses through the questionnaire.
- Complete and properly filled Google Form responses.

### ❖ Exclusion Criteria

- Individuals not diagnosed with hypertension
- Patients not receiving any antihypertensive treatment



- Incomplete, duplicate, or inconsistent responses in Google Forms
- Participants unwilling to share information or lacking basic knowledge of the subject

#### ❖ Hospital Visit

In order to have firsthand experience with adverse drug reaction monitoring and reporting systems in a clinical context, a hospital visit was undertaken as part of the pharmacovigilance study. Interactions with medical experts, such as pharmacists and hospital employees, were conducted throughout the visit in order to comprehend the procedure for recognizing, recording, and reporting adverse drug reactions (ADRs). The visit gave insights into how antihypertensive medications are prescribed in the real world and how medical professionals contribute to drug safety. Data was gathered about regularly prescribed drugs, including telmisartan and other antihypertensive medicines.

#### ❖ Data Collection Method

Structured questionnaires created with Google Forms were used to gather data for this investigation. To measure adverse drug reactions (ADRs) and pharmacovigilance awareness, two distinct questionnaires were created for patients and healthcare professionals. The antihypertensive medication therapy used to treat hypertension was the main topic of the study. Both multiple-choice and open-ended questions about drug use, adverse effects, frequently prescribed drugs, and ADR reporting procedures were included in the surveys. Pharmacists, as well as other medical professionals and patients, were the main recipients of the Google Forms. Since pharmacists are crucial to the normal practice of administering medications and monitoring side effects reported by patients, they were explicitly targeted.

Telmisartan was shown to be one of the most frequently given antihypertensive medications among the research population based on the responses gathered. Responses were gathered over a predetermined period of time after the forms were distributed online. For additional interpretation, the gathered data was then assembled, arranged, and examined using basic statistical techniques. Pharmacists provided the majority of the responses, which yielded insightful information on prescription trends. Based on the information gathered, telmisartan was discovered to be one of the most frequently given antihypertensive medications.

#### ❖ ADR Monitoring Form

In the current investigation, information about potential adverse drug reactions linked to antihypertensive medications used to treat hypertension was carefully gathered using an Adverse Drug Reaction (ADR) monitoring form. Essential information such as patient demographics (age, gender), suspected drug, dosage, mode of administration, length of therapy, description of adverse response, onset and duration of reaction, and any concurrent drugs were all included in the ADR form. Information about rechallenge was also taken into consideration, if it was accessible. The form was created using standard pharmacovigilance reporting standards to guarantee consistency and precision in data gathering. It assisted in the organized documentation of ADRs, which was then utilized for the Naranjo ADR Probability Scale's causality assessment.



<b>SUSPECTED ADVERSE DRUG REACTION REPORTING FORM</b>										
For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals										
<b>INDIAN PHARMACOPOEIA COMMISSION</b> (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Gurgaon-122002 www.ipcnic.in					<b>FOR AMC/NCC USE ONLY</b>					
<b>A. PATIENT INFORMATION</b>					AMC Report No. _____					
					Worldwide Unique No. _____					
1. Patient Initials _____			2. Age at time of Event or Date of Birth _____		3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>			12. Relevant tests/ laboratory data with dates		
4. Weight _____ Kgs										
<b>B. SUSPECTED ADVERSE REACTION</b>					13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)					
5. Date of reaction started (dd/mm/yyyy)										
6. Date of recovery (dd/mm/yyyy)										
7. Describe reaction or problem					14. Seriousness of the reaction (Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> Death (dd/mm/yyyy) <input type="checkbox"/> Congenital anomaly <input type="checkbox"/> Life threatening <input type="checkbox"/> Required intervention to prevent permanent impairment/damage <input type="checkbox"/> Hospitalization/Prolonged <input type="checkbox"/> Other (specify) 15. Outcomes <input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovered <input type="checkbox"/> Fatal <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown					
<b>C. SUSPECTED MEDICATION(S)</b>										
S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication
								Date started	Date stopped	
i										
ii										
iii										
iv										
S.No	9. Action Taken						10. Reaction reappeared after reintroduction			
As per C.	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										
11. Concomitant medical product including self medication and herbal remedies with therapy dates (Exclude those used to treat reaction)					<b>D. REPORTER DETAILS</b>					
17. Causality Assessment: Additional Information:					16. Name and Professional Address: _____					
					Pin: _____ E-mail: _____ Tel. No. (with STD code): _____ Occupation: _____ Signature: _____					
18. Date of this report (dd/mm/yyyy):										
<b>Confidentiality:</b> The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.										

### ❖ ADR Assessment Method

The reported adverse drug reactions (ADRs) were evaluated using the Naranjo ADR Probability Scale, a widely accepted and standardized tool for causality assessment.

The Naranjo Scale consists of a structured questionnaire with multiple parameters such as temporal association of drug administration, alternative causes, drug levels, dose-response



relationship, and previous patient experience with the drug.

Based on the total score obtained, ADRs were classified into the following categories:

- Definite ADR (score  $\geq 9$ )
- Probable ADR (score 5–8)
- Possible ADR (score 1–4)
- Doubtful ADR (score  $\leq 0$ )

This method provided a systematic approach to determine the likelihood that a drug caused a particular adverse effect, thereby improving the reliability of the study findings.

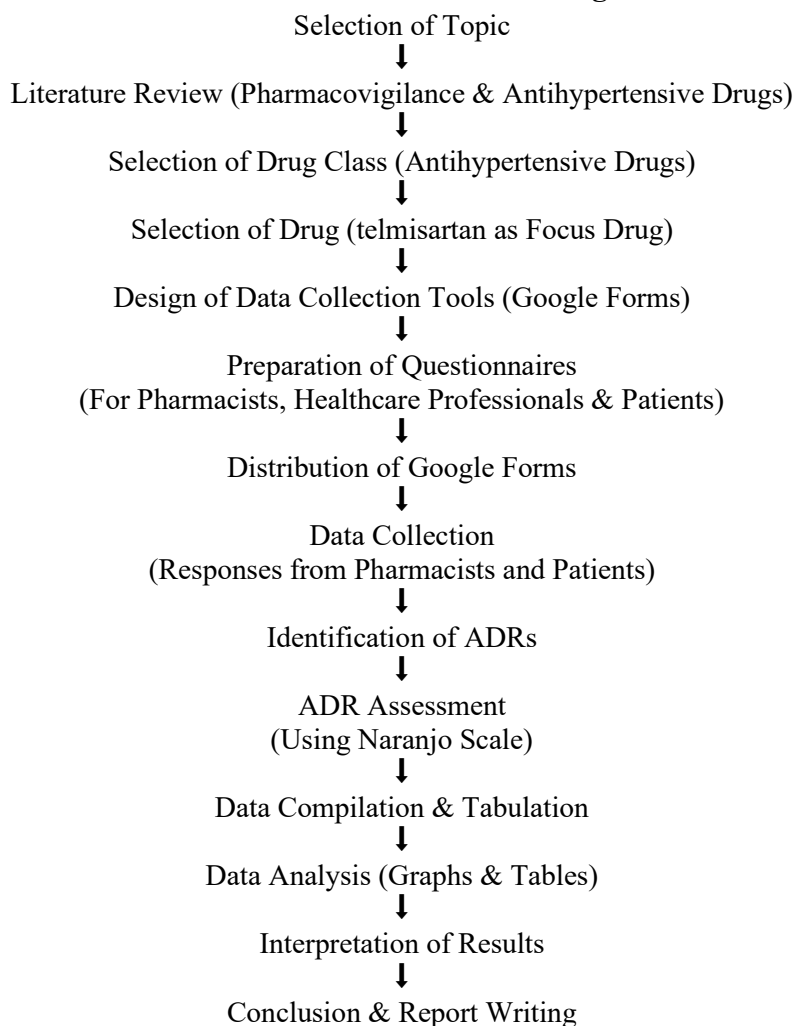
### ❖ Data Analysis

The collected data from Google Forms was compiled and organized systematically using spreadsheet tools. Every response was thoroughly examined and classified according to factors like

medication use, prescription frequency, adverse drug reaction incidence, and pharmacovigilance awareness.

The data was analysed using simple statistical methods, primarily focusing on frequency distribution and percentage analysis. This method made it easier to spot trends like the most often prescribed antihypertensive medications, frequently reported adverse drug reactions, and the degree of awareness among medical professionals. To improve comprehension and clarity, the data analysis was displayed utilizing visual aids such tables, pie charts, and bar graphs. These visual aids made it simpler to analyse the data and come to insightful conclusions.

- **The overall methodology adopted in the present study is summarized in the following flowchart**



## CH-5 RESULTS AND DISCUSSIONS

### ❖ Introduction

A total of 100 responses were collected, including 50 responses from pharmacists and 50 responses from patients. The data was collected using structured questionnaires to evaluate drug usage patterns, awareness of adverse drug reactions (ADRs), and reporting practices associated with antihypertensive drugs used in the management of Hypertension.

- **Pharmacist-Based Analysis (n = 50)**

#### 5.2.1 Profession

**Result:** All respondents belonged to the pharmacy profession.

**Discussion:** Inclusion of pharmacists ensures reliability of data, as they are directly involved in

dispensing antihypertensive drugs and interacting with patients.

#### 5.2.2 Name of Medical Store

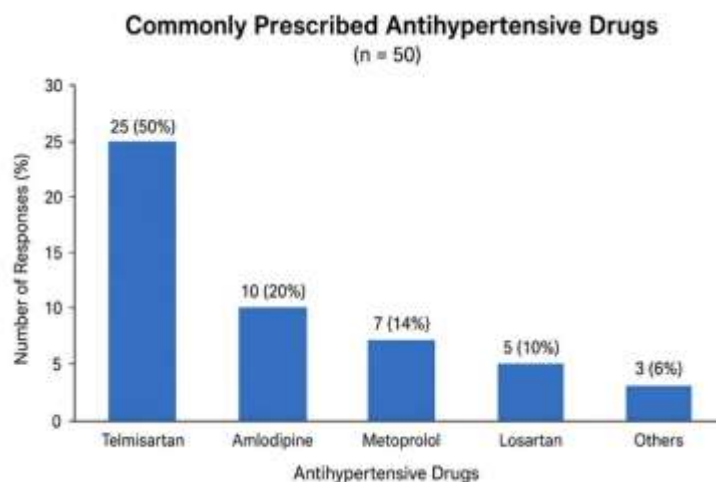
**Result:** Responses were collected from multiple community pharmacies across different locations.

**Discussion:** Data from different stores improves the diversity and generalizability of the study findings.

#### 5.2.3 Most Commonly Sold Antihypertensive Drug

**Result:** Telmisartan was found to be the most commonly sold antihypertensive drug.

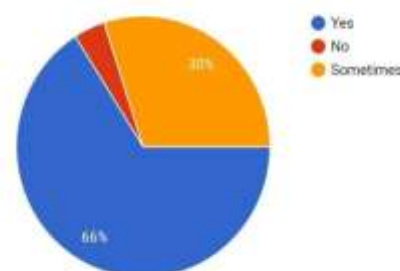
**Discussion:** This indicates its widespread use in the treatment of Hypertension, likely due to its efficacy and tolerability.



#### 5.2.4 Do You Inform Patients About Side Effects?

**Result:** A majority of pharmacists reported that they inform patients about possible side effects.

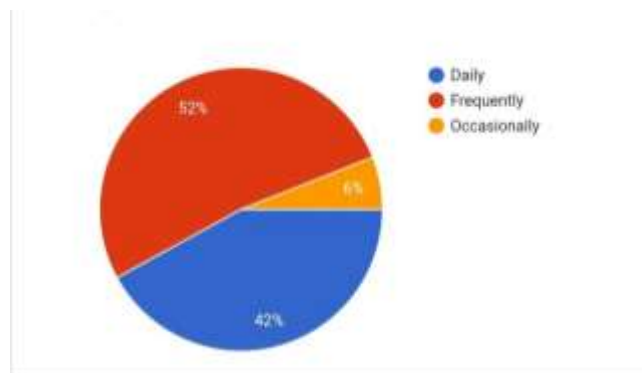
**Discussion:** This reflects good professional practice; however, patient-side data suggests that awareness is still lacking, indicating a communication gap.



#### 5.2.5 Frequency of BP Medicines Sold

**Result:** Antihypertensive medicines were reported to be sold frequently in most pharmacies.

**Discussion:** This highlights the high prevalence of hypertension and the need for long-term drug therapy, emphasizing the importance of pharmacovigilance.

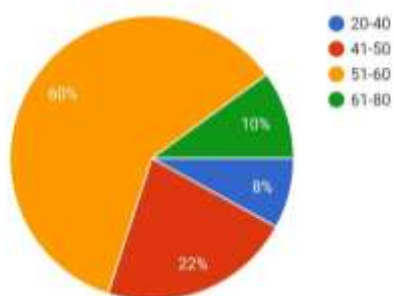


### 5.3 Patient-Based Analysis (n = 50)

#### 5.3.1 Age Distribution

**Result:** The study included patients from various age groups.

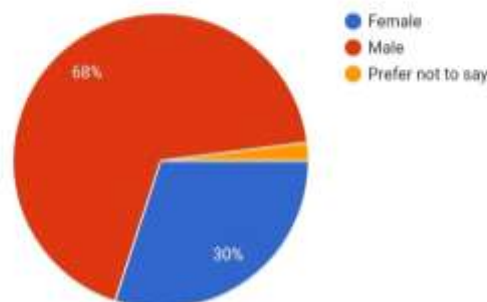
**Discussion:** Hypertension affects a wide age range, though it is more common in middle-aged and elderly populations.



#### 5.3.2 Gender Distribution

**Result:** Both male and female patients participated in the study.

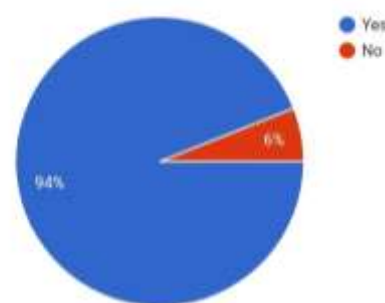
**Discussion:** Inclusion of both genders ensures balanced representation and reduces bias.



#### 5.3.3 Are You Taking Medication for High BP?

**Result:** Approximately 64% of patients reported that they are currently taking medication for high blood pressure.

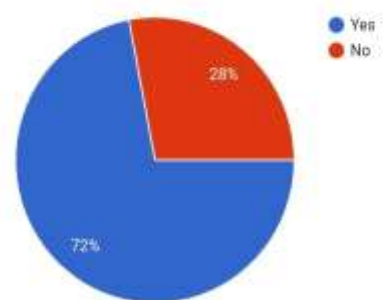
**Discussion:** This indicates a significant prevalence of hypertension requiring pharmacological management.



#### 5.3.4 Are You Aware That Medicines Can Cause Side Effects?

**Result:** A portion of patients were aware that medicines can cause side effects, while others were not.

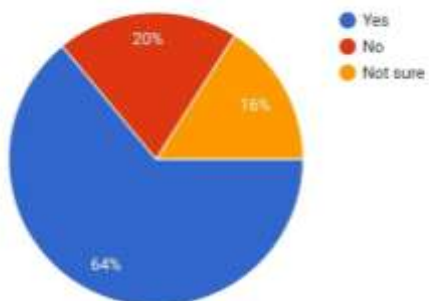
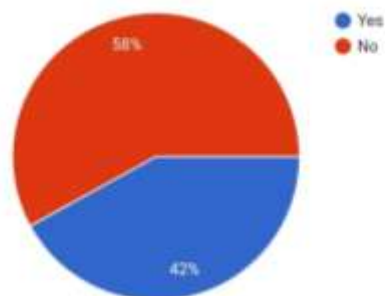
**Discussion:** Partial awareness indicates the need for better patient education regarding drug safety.



### 5.3.5 Have You Experienced Side Effects?

**Result:** Around 58% of patients reported experiencing side effects after taking medication.

**Discussion:** This suggests that ADRs are relatively common and should not be ignored in long-term therapy.



### 5.3.6 Did You Consult a Doctor/Pharmacist?

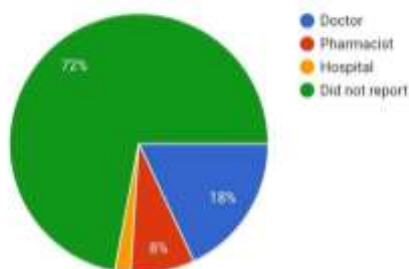
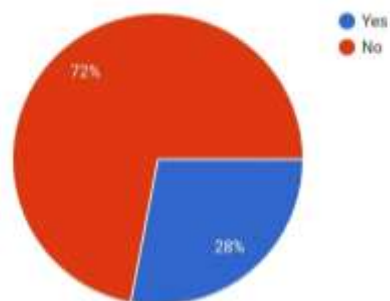
**Result:** Only a limited number of patients consulted healthcare professionals after experiencing side effects.

**Discussion:** This indicates that many patients neglect ADRs, which may lead to poor treatment outcomes.

### 5.3.8 Have You Ever Reported Side Effects?

**Result:** About 62% of patients reported that they have never reported any side effects.

**Discussion:** This confirms significant underreporting of ADRs, which is a major concern in pharmacovigilance.



### 5.3.7 Are You Aware That Side Effects Can Be Reported?

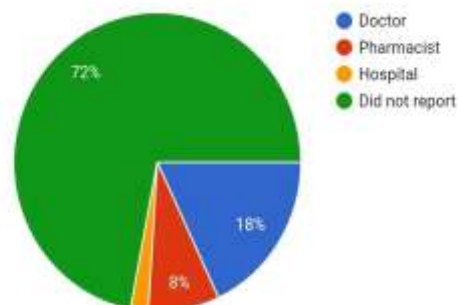
**Result:** A majority of patients were not aware that side effects can be formally reported.

**Discussion:** This clearly reflects a lack of awareness about pharmacovigilance systems.

### 5.3.9 If Yes, Where Did You Report?

**Result:** Very few patients reported ADRs, and those who did mainly reported to doctors or pharmacists.

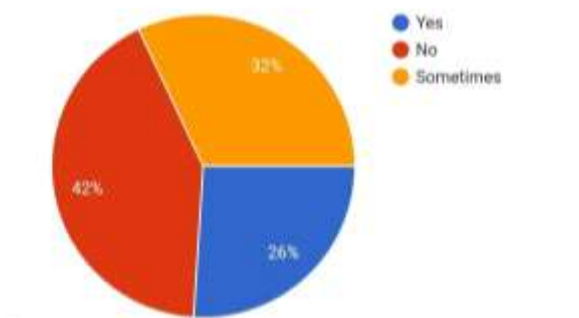
**Discussion:** Formal ADR reporting systems are underutilized, indicating lack of awareness and accessibility.



### 5.3.10 Do You Read or Ask About Side Effects?

**Result:** Some patients reported that they read or ask about side effects, while others do not.

**Discussion:** This variation shows inconsistency in patient behavior, emphasizing the need for better counseling.



## CH 6: Conclusion, Limitations & Future Scope

### CONCLUSION

The present study was carried out to evaluate adverse drug reactions (ADRs) associated with antihypertensive drugs and to assess awareness and reporting practices related to pharmacovigilance among pharmacists and patients in the management of Hypertension.

The findings of the study revealed that antihypertensive drugs such as telmisartan are widely used in clinical practice and are frequently dispensed in community pharmacies. A significant proportion of patients reported experiencing side effects during the course of treatment.

However, despite the occurrence of adverse drug reactions, the majority of patients did not report them. This was mainly due to lack of awareness regarding ADR reporting systems and the importance of pharmacovigilance. Although pharmacists were found to be aware and actively involved in patient counseling, this did not always result in proper reporting by patients.

Therefore, it can be concluded that while ADRs are common, there exists a substantial gap between occurrence and reporting. Strengthening

awareness and promoting pharmacovigilance practices among patients and healthcare professionals is essential to ensure drug safety and improve therapeutic outcomes.

### ❖ Limitations of the Study

- The study was conducted on a limited sample size (n = 100), which may not fully represent the entire population.
- Data collection was based on self-reported responses, which may be subject to bias or inaccuracies.
- The study was limited to a specific geographic area, which may affect the generalizability of the findings.
- Detailed clinical verification of reported adverse drug reactions was not possible.
- Lack of awareness among participants may have influenced the accuracy of responses related to pharmacovigilance.

### ❖ Future Scope

- Awareness programs and educational campaigns should be conducted to improve knowledge about pharmacovigilance among patients.
- Training programs for healthcare professionals can enhance ADR reporting practices.
- Larger-scale studies involving diverse populations can be carried out for more accurate analysis.
- Integration of digital tools and mobile applications can simplify ADR reporting.
- Collaboration between hospitals, pharmacies, and pharmacovigilance centers can strengthen drug safety monitoring systems.

### ❖ Recommendations

- Patients should be encouraged to report any unusual side effects to healthcare professionals.
- Pharmacists should take an active role in educating patients about ADR reporting systems.
- Simple and accessible reporting mechanisms should be promoted.

- Awareness regarding national pharmacovigilance programs should be increased.

## REFERENCES

1. Sutar M, Gawne D. Review article of study of drug regulatory approval process and comparative requirement of common technical document in Europe, USA and India in coordination with drug development process.
2. Emanuel EJ, Wendler D, Grady C. (2000). What makes clinical research ethical? *JAMA*. 283(20):2701-2711. 9. Weijer C, Miller PB. (2004). Ethical issues in research design.
3. Nimesh S. Pharmacovigilance program of review article Act a scientific pharmaceutical science. 2022.
4. Moore N (2001) The role of the clinical pharmacologist in the management of ADRs. *Drug Saf* 24(1):1–7
5. Jick H. Adverse drug reactions: the magnitude of the problem. *J Allergy Clin Immunol* 1984; 74:5557.
6. Hazell L, Shakir SAW. Under-reporting of adverse drug reactions: a systematic review. *Drug Saf* 2006; 29:385–396.
6. Alomar M, Tawfiq AM, Hassan N, Palaian S. Post marketing surveillance of suspected adverse drug reactions through spontaneous reporting: current status, challenges and the future. *Ther Adv Drug Saf* 2020.
7. Raj N, Fernandes S, Charyulu NR, Dubey A, Ravi GS, Hebbar S. Post market surveillance: a review on key aspects and measures on the effective functioning in the context of the United Kingdom and Canada. *Ther Adv Drug Safety*.
8. Alhawassi TM, Krass I, Pont LG. Antihypertensive-related adverse drug reactions among older hospitalized adults. *Int J Clin Pharm* 2018; 40:428–435.
9. Muntner, P., et al. (2018) Potent Impact of the 2017 ACC/AHA High Blood Pressure Guideline. *Circulation*, 137, 109-118
10. England Public Health. Health matters: combating high blood pressure. Public Health England, 2017
11. Organisation WH. World Health Organization (2013), A global brief on hypertension. Report. 2013 April 2013
12. 13. Wiene W, Entzeroth M, van Meel JCA, et al. 2000. A review on telmisartan: a novel, long-acting angiotensin II-receptor antagonist. *Cardiovasc Drug*
13. tangier J, Su C-APF, Roth W. 2000. Pharmacokinetics of orally and intravenously administered telmisartan in healthy young and elderly volunteers and in hypertensive patients. *J Int Med Res*
14. Takai S, Kirimura K, Jin D, et al. 2005. Significance of angiotensin II receptor blocker lipophilicities and their protective effect against vascular remodelling. *Hypertense*.
15. Benson SC, Pershadsingh HA, Ho CI, Chittiboyina A, Identification of telmisartan as a unique angiotensin II receptor antagonist with selective PPAR- $\gamma$ -modulating activity, Preclinical study, California State University, Hayward, California, USA; Bethesda Pharmaceuticals, Inc., Bakersfield, California, USA, *Hypertension* 2004;
16. Schupp M, Janke J, Clasen R, Unger T, Kintscher U, Angiotensin type 1 receptor blockers induce peroxisome proliferator activated receptor- $\gamma$  activity, Charite-University, Berlin, Germany, *Circulation* 2004;
17. Benson SC, Pershadsingh HA, Ho CI, Chittiboyina A, Desai P, Pravenec M, et al. Identification of telmisartan as a unique angiotensin II receptor antagonist



- withselective PPARgamma-modulating activity. Hypertension. (2004)
18. Jung AD, Kim W, Park SH, Park JS, Cho SC, Hong SB, et al. The effect of telmisartan on endothelial function and arterial stiffness in patients with essential hypertension. *Korean Circ J.* (2009)
  19. World Health Organization. Fact sheet: Safety of medicines. A guide to detecting and reporting adverse drug reactions. Why health professionals need to take action, 2002.
  20. Pharmacovigilance Risk Assessment Committee: PRAC strategy on measuring the impact of pharmacovigilance activities. 2016
  21. World health organization. Pharmacovigilance: Ensuring the safe use of medicines. World Health Organ. 2004.
  22. Shamna M, Dilip C, Ajmal M, Linu PM, Shinu C, Jafer CP. A prospective study on Adverse Drug Reactions of antibiotics in a tertiary care hospital. *Yahiya Mohammed b. Saudi Pharmaceutical Journal* 2013.

**HOW TO CITE:** Sakshi Jadhav, Dhanashri Mali, Gauri Chaudhari, Sakshi Dawange, Vaishali Rawal and Dr. M. R. N. Shaikh, A Pharmacovigilance Study of Antihypertensive Drugs with Reference to ADR Reporting and Patient Awareness in Hypertension, *Int. J. of Pharm. Sci.*, 2026, Vol 4, Issue 6, 200-217, <https://doi.org/10.5281/zenodo.20486646>

