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# A Study on Antihypertensive Safety: Enhancing Public Adverse Drug Reactions Reporting

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**ABSTRACT**:**Aim**: To enhance public knowledge and attitudes towards antihypertensive drug monitoring, detection, and reporting, while also developing various steps for improving patient safety and public health. **Method:** A survey was conducted on over 250 people in Ernakulam district, covering demographics, ADR knowledge, reporting, and applications, while collecting and analyzing antihypertensive drug prescriptions. **Result**: Out of 38 anti-hypertensive drugs, 14 are combinations, with Telmisartan being the most widely used. The most vulnerable age group is 51-60 years, with females experiencing more adverse drug reactions (ADRs) and most people are unaware of this. **Conclusion**: The study assessed public knowledge on pharmacovigilance, ADR detection, assessment, monitoring, and reporting and various steps to enhance patient safety and public health.

**KEYWORDS:** Hypertension, Pharmacovigilance, ADR , Gamification.

## I. INTRODUCTION

Hypertension is a prevalent chronic condition affecting millions worldwide, and antihypertensive medications are crucial for managing it. However, underreporting of adverse drug reactions (ADRs) is a significant challenge. A project proposes using gamification to enhance public reporting of ADRs, improving pharmacovigilance efforts. The study will assess the impact of gamification on reporting rates, user engagement, and data quality. This project aims to improve medication safety and patient care in hypertension management, potentially inspiring innovative approaches to pharmacovigilance in other therapeutic areas.[11]

PHARMACOVIGILANCE

Pharmacovigilance, defined by WHO as the science of detecting, assessing, understanding, and preventing adverse effects of medicines, has gained significant importance in the pharmaceutical sector. Launched in 2010, the Pharmacovigilance Programme of India (PvPI) was later designated as a Collaborating Center for Pharmacovigilance in Public Health Programs & Regulatory Services.[8]

HYPERTENSION

Hypertension is a common condition where blood pressure is too high, measured without symptoms. It can be treated through lifestyle changes like healthier eating, quitting smoking, and exercise. Risk factors include poor diets, obesity, smoking, nicotine, alcohol, age over 65, hypertension family history, and co-occurring conditions. Antihypertensive medications can cause adverse drug reactions, but research helps choose appropriate medications, improve treatment adherence, and minimize financial burden.[11]

ADVERSE DRUG REACTION

Adverse drug reactions (ADRs) are a significant issue in modern medicine, especially in aging populations and advanced therapies. Prescribers can prevent ADRs by understanding a patient's past experiences, avoiding sensitive patient groups, administering lower-risk treatments, co-administration, and monitoring blood test results. However, spontaneous reporting is crucial for pharmacovigilance.[11]

OBJECTIVES

1. To study the knowledge of public regarding PvPI and improve ADR reporting.
2. To study the attitude regarding adverse drug reaction monitoring, detection, reporting of antihypertensives.
3. Various steps to improve underreporting.

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## II. METHODOLOGY

Study area: The primary cities of Kerala's central Ernakulam district served as the study's locations. The 3,068 square kilometer Ernakulam district is situated in India's Western Coastal Plains. The state's main metropolitan area is the Ernakulam district.

Study design and Data collection: A three-month study was conducted on more than 250 people. This study was a prospective, questionnaire-based survey to increase awareness of adverse drug reactions (ADRs) or reporting ADR associated with antihypertensive using online survey (Google form), paper survey technique and face-to-face communication survey method. A self-designed questionnaire containing 20-questions was created and validated, it included all relevant information such as the name of the person, age, gender, qualification and whether the individuals were aware of ADRs, it's reporting, pharmacovigilance & ADR related to Anti-hypertensive. Prescriptions containing Anti-hypertensive drugs were also collected. Sensitization was given to the public who were not aware of pharmacovigilance, adverse drug reactions, and its reporting.

Data Analysis: The information gleaned from the prescription analysis and survey was analyzed and simplified into an excel spreadsheet, graphically displayed.

## III. RESULTS & DISCUSSION

The present prospective study was conducted on more than 250 people for 3 months in and around Ernakulam district. This study was a questionnaire-based survey to increase awareness of adverse drug reactions (ADRs) and improve ADR reporting associated with antihypertensive drug using online survey (Google form), paper survey technique and face-to-face communication survey method. We had also collected prescriptions containing anti-hypertensive's drug. The results of prescription analysis were graphically represented as fig.1. After analyzing the prescriptions, we got 38 anti- hypertensive's drugs among them 14 combinations.

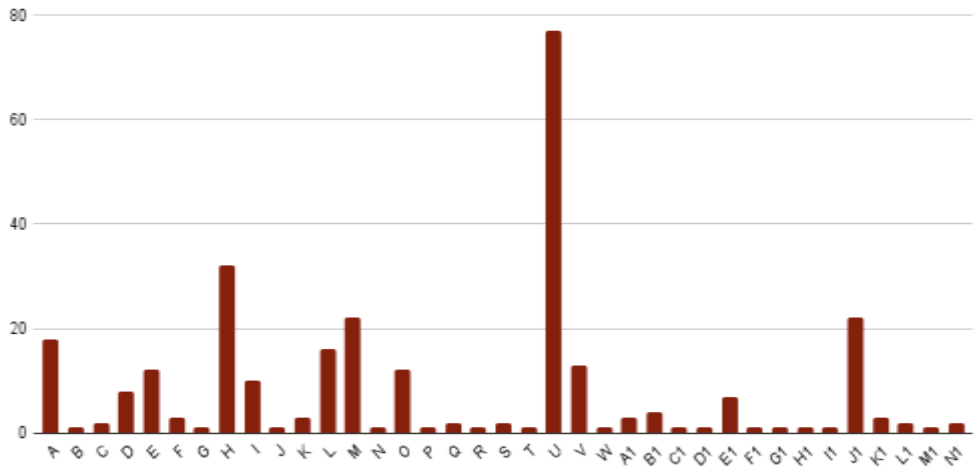


**Fig.1 Antihypertensive Drug Frequency Rate (**A-Amlodipine, B- Atenolol, C-Azelnidipine, D-Bisoprolol, E-Bisoprolol Fumarate, F-Carvedilol, G-Chlorthalidone, H-Clinidipine, I-Clonidine, J-Eplerennone, K-Furosemide, L-Losartane, M-Metoprolol, N-Moxonidine, O-Nebivolol, P Nicardipine, Q-Nifidipine, R-Olmesartan, S-Olmesartan medoxomil, T-Prazocin, U-Telmisartane, V-Torsemide, W-Verapamil, A1-Amiloride & Furosemide, B1- Amlodipine & Atenolol, C1- Amlodipine & Metoprolol, D1-Olmesartan & Chlorthalidone, E1- Olmesartan medoxomil & Amlodipine, F1- Olmesartan medoxomil & Chlorthalidone, G1- Perindopril & Amlodipine, H1- Telmisartan & Amlodipine, I1-Telmisartan & Chlorthalidone, J1-Telmisartan & Clinidipine, K1- Telmisartan &Hydrochlorthiazide, L1- Telmisartan & Metoprolol, M1- Telmisartan & Metoprolol Succinate, N1- Telmisartan, Amlodipine &Hydrochlorthiazide.)

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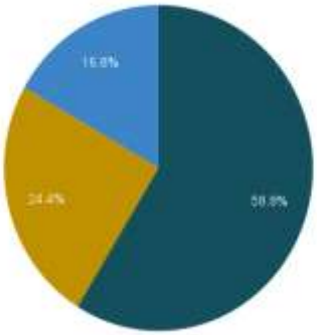

**Fig.2 Drug Frequency Rate**

From fig.2 it is clear that Telmisartan was the most widely used anti- hypertensive drug followed by Clinidipine & Metoprolol respectively.

Telmisartan is an angiotensin II receptor antagonists. It blocks the action of certain natural substances that tighten the blood vessels, allowing the blood to flow more smoothly and the heart to pump more efficiently.It is used to decrease the chance of heart attack, stroke, etc.

Cilnidipine is a calcium channel blocker used to treat hypertension and angina. It works on the L-type calcium channels of blood vessels, blocking incoming calcium and suppressing vessel contraction, reducing blood pressure. It also works on the N-type calcium channel at the end of the sympathetic nerve, inhibiting norepinephrine emission and increasing stress blood pressure.

Metoprolol is a medication classified as a beta blocker, primarily prescribed to manage conditions like high BP, chest pain (angina), and heart failure. By selectively blocking the action of adrenaline on beta receptors in the heart and blood vessels, Metoprolol reduces heart rate and BP thus, decreasing the work load on heart. This leads to more efficient pumping blood and a decrease in oxygen demand of the heart muscle; it can help alleviate symptoms such as chest pain and shortness of breath

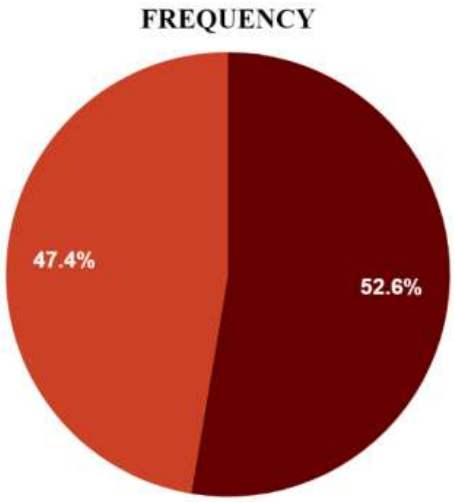


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**Fig. 3 Gender frequency rate**

Females experienced more ADRs than males. 52.6 % belong to females & 47.4 % belong to male and were graphically represented in fig.3.

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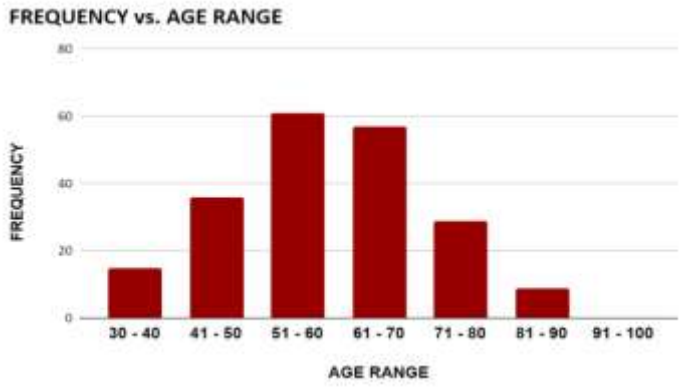


**Fig.4 Age frequency rate**

The most vulnerable age group affected by hypertension was 51-60 years followed by 61-70 years, 41-50 years, 71-80 years and 31-40 and above 80 years were presented graphically in fig. 4.

The results of survey questionnaire are presented below:

Out of 252 responses, 141 were health care professionals whereas 111 where general public.

| Sl No. | Questions | Yes (%) | No (%) |
|---|---|---|---|
| 1 | Do you know about Pharmacovigilance? | 56.3 | 43.7 |
| 2 | Do you know that drugs have bad effects as well as good effects? | 95.6 | 4.4 |
| 3 | Do you know the difference between ADR and side effects? | 61.1 | 38.9 |
| 4 | Do you know the medicines may have ADR after administration? | 69.4 | 30.6 |
| 5 | Do you know that even common people can report ADR? | 62.3 | 37.7 |
| 6 | Do you know how to report an ADR? | 40.1 | 59.9 |
| 7 | Do you know where to report an ADR? | 37.7 | 62.3 |
| 8 | Do you know ADR reporting helpline number? | 23.8 | 76.2 |
| 9 | Do you think ADR reporting will improve patient safety? | 80.6 | 19.4 |
| 10 | Do you know that hospitals have ADR reporting forms? | 60 | 40 |
| 11 | Are you familiar with the ADR reporting process? | 26.6 | 73.4 |
| 12 | Have you ever seen an ADR reporting form? | 27.8 | 72.2 |
| 13 | Have you ever reported an ADR? | 14.7 | 85.3 |
| 14 | Are you afraid of reporting ADR? | 17.5 | 82.5 |
| 15 | Have you ever seen an ADR? | 44 | 56 |
| 16 | Have you ever used any ADR reporting applications? | 17.9 | 82.1 |
| 17 | Do you think ADR reporting applications are useful? | 86.9 | 13.1 |
| 18 | Will you report ADR if you get any assessable application? | 80.6 | 19.4 |

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| | | | |
|---|---|---|---|
| 19 | Do you know about gamification? | 35.3 | 64.7 |
| 20 | Do you think adding gaming elements would make you more likely to report ADR? | 79.4 | 20.6 |

The survey findings revealed that a significant portion of the population lacks awareness regarding the procedures for reporting Adverse Drug Reactions (ADRs), including the appropriate timing, methods, and reporting locations. Moreover, the process itself appears overly complex to many respondents. Additionally, there is a notable lack of public awareness surrounding ADR reporting, indicating a need for widespread education on this critical aspect of drug safety.

Here are some methods to enhance underreporting of Adverse Drug Reactions (ADRs) with descriptions:

1. Gamification
2. Patient Education Campaigns
3. Healthcare Provider Training
4. Simplified Reporting Processes
5. Incentive Programs
6. Feedback Mechanisms**.**
7. Integration with Electronic Health Records (EHRs
8. Collaboration with Pharmacovigilance Programs
9. Public Awareness Campaigns
10. Peer Support Networks
11. Continuous Monitoring and Evaluation

## ❖ GAMIFICATION

Gamification in pharmacovigilance involves applying game design elements and principles in the context of drug safety monitoring to engage stakeholders, improve reporting, and enhance surveillance of adverse drug reactions (ADRs). Pharmacovigilance is crucial for monitoring the safety of drugs post-marketing and ensuring timely detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

**Benefits:**

The gamification platform raises awareness among the general public about the importance of ADR reporting for improving medication safety and healthcare quality. By integrating ADR reporting into everyday scenarios, the platform encourages players to become more vigilant about medication-related issues in their communities. Offering gentle reminders for medication adherence, dietary adjustments, and lifestyle enhancements, it empowers users with daily points, fostering a sense of accomplishment and progression. Positioned within a dynamic scoreboard, users are bestowed with rewards based on their accrued points, fostering a sense of camaraderie and motivation towards collective health and well-being.

**Additional Considerations:**

- Enhanced Engagement: Our app distinguishes itself from existing ADR reporting platforms by offering a more captivating and interactive user experience.
- Accessibility: Designed to be readily accessible to the general public, our app ensures that anyone can easily engage with and contribute to medication safety efforts.
- User-Friendly Interface: With a simple and intuitive design, our app prioritizes ease of use, making it effortless for individuals of all backgrounds to navigate and utilize its features.
- Universal Compatibility: Compatible with all Android versions, as well as accessible to non-Android users and those on Windows platforms, our app ensures inclusivity and broad reach across diverse user demographics.

## ❖ PATIENT EDUCATION CAMPAIGNS:

Develop educational materials for patients regarding the importance of reporting ADRs. Clearly explain how to recognize and report ADRs, emphasizing the role of patients in ensuring drug safety.

## ❖ HEALTHCARE PROVIDER TRAINING:

Conduct training sessions for healthcare professionals to improve their awareness of ADR reporting systems. Provide guidance on recognizing, documenting, and reporting ADRs effectively.

## ❖ SIMPLIFIED REPORTING PROCESSES:

Streamline the ADR reporting process by simplifying forms and procedures. Make reporting accessible through multiple channels such as online platforms, mobile apps, and toll-free hotlines.

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❖ **INCENTIVE PROGRAMS**:

Implement incentive programs for both patients and healthcare professionals to encourage ADR reporting. Rewards, such as vouchers or recognition, can motivate individuals to participate in reporting efforts.

❖ **FEEDBACK MECHANISMS**:

Establish mechanisms to provide feedback to reporters about the outcome of their ADR reports. This could involve acknowledgment of receipt, updates on investigations, and summaries of actions taken in response to reported ADRs.

❖ **INTEGRATION WITH ELECTRONIC HEALTH RECORDS (EHRS)**:

Integrate ADR reporting functionalities into electronic health record systems used by healthcare providers. This facilitates seamless documentation and reporting of ADRs during routine clinical encounters.

❖ **COLLABORATION WITH PHARMACOVIGILANCE PROGRAMS**:

Partner with pharmacovigilance programs and regulatory agencies to leverage their expertise and resources in promoting ADR reporting. Collaborative efforts can enhance the reach and effectiveness of ADR reporting initiatives.

❖ **PUBLIC AWARENESS CAMPAIGNS**:

Launch public awareness campaigns through various media channels to raise awareness about the importance of ADR reporting. Use compelling narratives and real-life examples to illustrate the impact of ADRs on patient safety.

❖ **PEER SUPPORT NETWORKS**:

Foster peer support networks among patients and healthcare professionals to facilitate open discussions about ADRs and share experiences related to reporting. Peer support can help reduce stigma and encourage reporting.

❖ **CONTINUOUS MONITORING AND EVALUATION**:

Implement continuous monitoring and evaluation mechanisms to assess the effectiveness of ADR reporting initiatives. Regularly review reporting rates, feedback from stakeholders, and outcomes of reported ADRs to identify areas for improvement.

## IV. CONCLUSION

The study aimed to understand public knowledge and attitudes towards adverse drug reaction monitoring, detection, and reporting of antihypertensive drugs. Over 250 people participated and collected about 300 prescriptions containing anti-hypertensives drugs. The study found that the public lacks knowledge about pharmacovigilance and ADR reporting due to inadequate training and education. The complexity of the reporting process and uncertainty about the cause of ADRs may also contribute to underreporting. To address these issues, the study provided sensitization on Pharmacovigilance, ADR reporting, and gamification. The gamification-enhanced reporting system increased public participation and quality reports, leading to better detection of adverse reactions and better patient outcomes. The interactive and rewarding elements of gamification also improved patient adherence to medication regimens.

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