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Comprehensive Safety Monitoring and Causality Assessment of Antihypertensive Medications in the Cardiology Department of a Tertiary Care Hospital

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ABSTRACT

Aim: To ensure the safe and effective use of antihypertensive medications by identifying, assessing, and managing adverse events associated with their administration.

Objective: To analyze adverse drug reactions (ADRs) in the cardiology department of a tertiary care hospital in Hyderabad, Telangana, India.

Methodology:A prospective, observational, cross-sectional study was conducted over 3 months in the cardiology department of Tertiary Care Hospital in Hyderabad, Telangana, India. ADRs occurring in the ward were closely monitored, and collected reports were analyzed for demographic profiles, types of ADRs, occurrence, causative drugs, severity assessment, and causality.

Results:A total of 38 hypertensive patients, meeting the inclusion and exclusion criteria, were observed and assessed over the study period. The prevalence of ADRs was predominantly higher in older patients, particularly those aged 61-80 years (44.7%). Diuretic drugs were most frequently implicated (47.3%), followed by beta-blockers (18.4%), and other medications such as telmisartan, Spironolactone, and amlodipine (34.2%). The majority of the reactions were moderate in severity.

Conclusion: This pharmacovigilance study provides a profile of ADRs associated with antihypertensive medications. The findings suggest that diuretics are most commonly linked to significant ADRs. These data can assist physicians in making more informed prescription decisions, ultimately enhancing patient safety and treatment efficacy.

Keywords: Antihypertensive medications, Adverse drug reactions (ADRs), Pharmacovigilance, Cardiology, Tertiary care hospital, Diuretics

I. INTRODUCTION:

Adverse drug reactions (ADRs) are a significant concern in clinical practice, posing considerable risks to patient safety and contributing to morbidity and mortality. The World Health Organization (WHO) defines an ADR as "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function" [(1)]. In the United States, ADRs are among the leading causes of death, with 6.7% of hospitalized patients experiencing significant ADRs, highlighting the global impact of this issue [(2)].

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem, is essential for ensuring medication safety [(3)]. In India, the Pharmacovigilance Programme of India (PvPI) has established a network of ADR Monitoring Centers (AMCs) to collect and analyze ADR data, aiming to enhance drug safety protocols across the nation [(4)].

Despite these efforts, ADR monitoring in India is still developing. Studies have reported that a significant proportion of patients experience ADRs, with some leading to hospitalizations or even death [(5)]. This underscores the need for continuous education and awareness among healthcare professionals regarding their roles in identifying, managing, and reporting ADRs.

Hypertension, a chronic condition requiring long-term medication, often necessitates the use of antihypertensive drugs, which can lead to various ADRs. Given the asymptomatic nature of hypertension and the lifelong need for treatment, monitoring the safety profiles of antihypertensive medications is crucial. This is particularly important in tertiary care hospitals, where patients with complex and severe conditions are treated (6).

The objective of this study is to conduct comprehensive safety monitoring and causality assessment of antihypertensive medications in the cardiology department of a tertiary care hospital. By closely tracking and analyzing ADRs, this study

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aims to identify the prevalence, severity, and causative factors of ADRs associated with antihypertensive drugs. The findings will contribute to improved patient safety and inform better prescribing practices.

Through rigorous pharmacovigilance efforts, including the use of causality assessment tools like the Naranjo scale, this study seeks to provide valuable insights into the ADRs linked to antihypertensive medications. The results will help healthcare professionals make informed decisions, ultimately enhancing the quality of care for patients with hypertension[7].

II. METHODOLOGY:

Study Design and Setting

This study employed a prospective, observational, cross-sectional design conducted in the cardiology department of a tertiary care hospital in Hyderabad, Telangana, India. The study duration spanned over 3 months to capture a comprehensive view of adverse drug reactions (ADRs) associated with antihypertensive medications.

Following informed consent, a total of 38 patients participated in the study over three months. Data collection was conducted using an ADR monitoring form in accordance with the Central Drugs Standard Control Organization (CDSCO), Government of India recommendations.

Inclusion and Exclusion Criteria

The inclusion criteria encompassed hypertensive patients of both genders, aged 18 years and above, who were admitted to the cardiology department during the study period and were prescribed antihypertensive medications. Patients with incomplete medical records or those unable to provide informed consent were excluded from the study.

Data Collection Procedures

Relevant demographic information (age, gender), medical history (comorbidities), and details of antihypertensive medications prescribed were recorded. A standardized form was used to document suspected ADRs, including their onset, duration, severity, and outcomes.

Tools for ADR Monitoring and Causality Assessment

The Naranjo Adverse Drug Reaction Probability Scale was employed to assess the causality of suspected ADRs. This scale categorizes the likelihood of an ADR being attributable to a specific medication into categories such as definite, probable, possible, or unlikely based on criteria related to temporal sequence, alternative explanations, and previous documentation.

III. RESULTS:

Demographic Profile of the Study Population

Table 1 presents the Gender Distribution of patients who experienced adverse drug reactions (ADRs) related to antihypertensive medications during the three-month study period.

Table 1: Gender Distribution in Study Population

Gender	No. of Patients
Male	24
Female	14

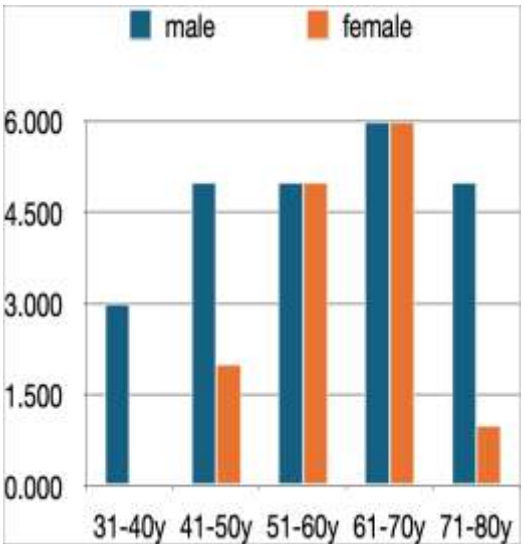

Fig1: Gender and Age wise distribution of patients

Types and Frequencies of Observed ADRs

A total of 38 patients experienced adverse drug reactions (ADRs) attributed to antihypertensive medications during the study period. The most frequently observed ADRs were hypotension, hypokalemia, constipation, hyponatremia, elevated creatinine, sinus bradycardia, and dizziness. Table 2 summarizes the types and frequencies of ADRs observed.

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Table 2: Types and Frequencies of Observed ADRs

S.No	Type of ADR	No. of Subjects	Percentage
1.	Hypokalemia	13	22.8%
2.	Hypotension	11	19.2%
3.	Constipation	14	24.5%
4.	Shortness of Breath	2	3.5%
5.	Hyponatremia	6	10.5%
6.	Increased Creatinine	2	3.5%
7.	Sinus Bradycardia	2	3.5%
8.	Decreased Appetite	1	1.75%
9.	Black Stools, Loose Stool	1	1.75%
10.	Giddiness and Numbness	1	1.75%
11.	Diarrhea	1	1.75%
12.	Renal Dysfunction	1	1.75%
13.	Increased Uric Acid	1	1.75%

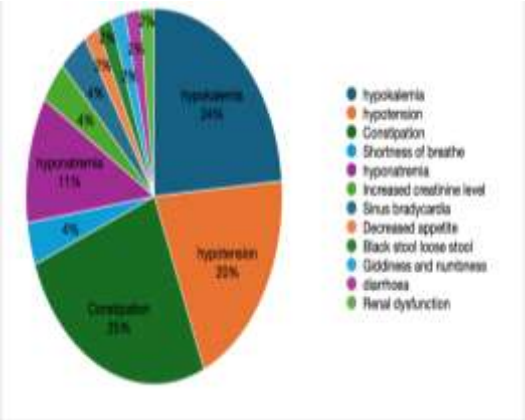

Fig 2: Types and Frequencies of Observed ADRs

Age-wise Distribution of Patients with ADRs

The table 3 categorizes the study population into different age groups and shows the number of patients within each group who experienced adverse drug reactions (ADRs). It demonstrates that patients aged 61-70 years had the highest incidence of ADRs, followed by those aged 51-60 years, providing insight into the age-related patterns of ADR occurrence

Table 3: Age-wise Distribution of Patients with ADRs

Age Group	No. of Patients with ADRs
30-40	2 (5.2%)
41-50	7 (18.4%)
51-60	10 (26.3%)
61-70	12 (31.5%)
71-80	5 (13.1%)

Causality Assessment of ADRs

Table 4 summarizes the causality assessment of ADRs using Naranjo's probability scale.It categorizes ADRs as possible or probable based on the likelihood of the drug being the cause of the reaction. The predominance of probable ADRs (71.1%) suggests strong evidence linking antihypertensive medications to the observed adverse reactions.

Table 4: Causality Assessment of ADRs

Type of ADR	No. of Subjects	Percentage
Possible	11	28.9%
Probable	27	71.1%
Definite	0	0%
Unlikely	0	0%

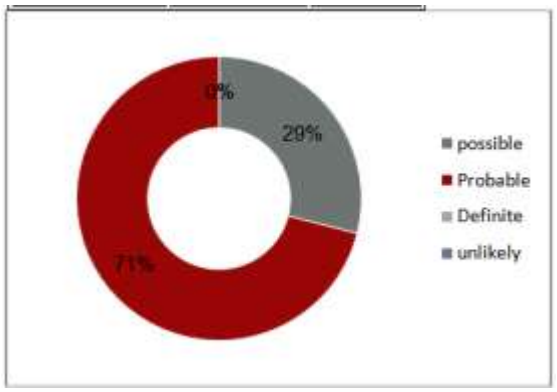

Fig 3: Causality Assessment of ADRs

Severity Assessment of ADRs

Table 5 presents the severity assessment of ADRs observed in the study population.It categorizes ADRs as mild, moderate, or severe based on the impact on patients. The absence of severe ADRs and the predominance of mild and moderate reactions indicate that most ADRs were

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manageable and did not lead to serious medical consequences.

Table 5: Severity Assessment of ADRs

Severity	No. of ADRs	Percentage of ADRs
Mild	25	65.8%
Moderate	13	34.2%
Severe	0	0%
Total	38	100%

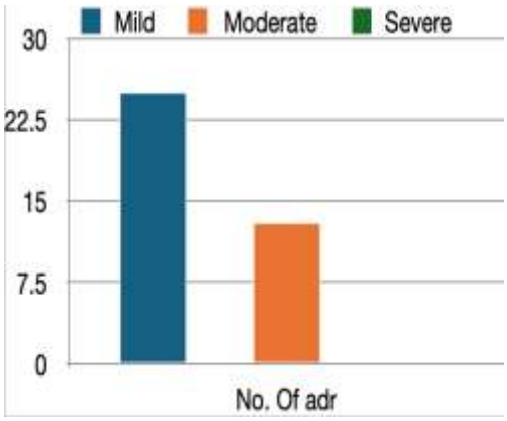

Fig 4: Severity Assessment of ADRs

Drugs Responsible for ADRs

Table 6 lists the specific antihypertensive medications and their associated ADRs observed during the study.It highlights common medications like Furosemide (Lasix) and Metoprolol (Met XL) that were frequently implicated in causing ADRs such as hypotension, hypokalemia, and constipation. This information is crucial for clinicians in understanding the risks associated with different medications.

Table 6: Drugs Responsible for ADRs

Suspected Drug	Associated ADRs	Frequency	% of Patients
Lasix (Furosemide)	Hypotension, Hypokalemia, Constipation, Hyponatremia, Increased Creatinine	18	47.3%
Met XL (Metoprolol)	Hypotension, Sinus Bradycardia, Constipation	7	18.4%
Telma (Telmisartan)	Hyponatremia, Hyperuricemia, Constipation, Decreased Appetite	4	2.6%
Lasilactone	Hypokalemia, Dizziness, Increased Uric Acid	1	10.5%
Amlong (Amlodipine)	Constipation, Edema, Black Stool, Loose Stool, Melena	2	5.2%
Aldactone (Spironolactone)	Constipation, Hypotension, Hyperkalemia	4	10.5%
Cardivas (Carvedilol)	Numbness in Upper and Lower Limbs, Hypotension	2	5.2%
Cinod (Cilnidipine)	Hypokalemia	2	5.2%
Nebister (Nebivolol)	Sinus Bradycardia	1	2.6%
Starpress XL (Metoprolol Succinate)	Shortness of Breath, Constipation	1	2.6%
Cilacar (Cilnidipine)	Hypotension, Insomnia	1	2.6%
Bisonext (Bisoprolol and Amlodipine)	Hypotension, Constipation	1	2.6%
Clonidine	Shortness of Breath, Vision Change, Syncopal Event	1	2.6%

Management of ADRs

Table 7 outlines the management strategies employed for patients experiencing ADRs during the study.It categorizes management approaches such as drug withdrawal, dose reduction, or addition of other medications based on the severity and nature of the ADRs. The variety of management strategies reflects the individualized approach to mitigating ADRs in clinical practice.

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Table 7: Management of ADRs

Management of ADR	No. of Subjects
Drug Withdrawn	18
Drug Withdrawn; Other Drugs Added	1
No Change; Other Drugs Added	3
Drug Dose Reduced	6
Drug Dose Reduced; Other Drugs Added	3
No Change	7

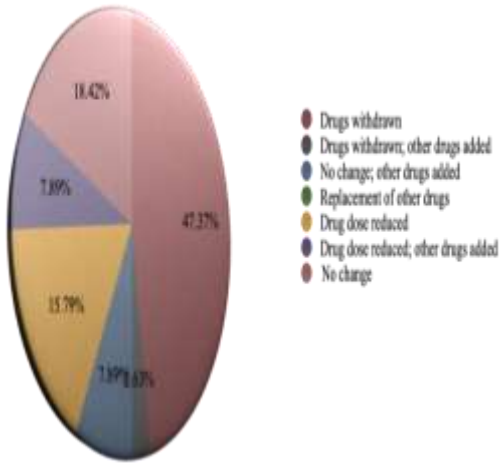

Fig 5: Management of ADRs

IV. DISCUSSION:

The findings of this study highlight several critical aspects regarding adverse drug reactions (ADRs) associated with antihypertensive medications in the cardiology department of a tertiary care hospital. Firstly, Furosemide (Lasix) emerged as the predominant culprit, accounting for 47.3% of all ADRs observed. This aligns with its known side effects such as hypotension, hypokalemia, and constipation, which were prominently reported in this study. Metoprolol (Met XL), Telmisartan (Telma), and Spironolactone (Aldactone) also exhibited notable associations with ADRs, emphasizing the variability in adverse effects across different classes of antihypertensive drugs.

Causality assessment using Naranjo's probability scale indicated that a significant majority (71.1%) of ADRs were categorized as probable, suggesting a strong likelihood of these medications being responsible for the observed adverse reactions. This underscores the importance of vigilant monitoring and prompt intervention in clinical settings to mitigate potential harm associated with antihypertensive therapy.

Severity assessment revealed that the majority of ADRs were mild (65.8%), requiring minimal medical intervention, while a smaller proportion were moderate (33.3%). Notably, no severe ADRs were reported in this study, indicating that while ADRs are prevalent, they predominantly manifest as manageable conditions rather than severe medical emergencies.

When compared to previous studies, our findings corroborate the global pattern of ADRs associated with antihypertensive medications. Similar studies have reported Furosemide and Metoprolol among the top medications linked to ADRs, albeit with variations in specific adverse effects and their frequencies. This consistency underscores the reproducibility of ADR profiles across different patient populations and healthcare settings [10-12].

The implications of this study for clinical practice are manifold. Healthcare providers need to be vigilant in monitoring patients on antihypertensive therapy, especially those prescribed Furosemide and Metoprolol, due to their higher propensity for causing ADRs. Routine pharmacovigilance practices, including regular assessment of patient symptoms and laboratory parameters, are crucial in the early detection and management of ADRs to prevent complications and improve patient outcomes [13-17].

Furthermore, the predominance of mild to moderate ADRs highlights the importance of patient education regarding the potential side effects of antihypertensive medications. Clinicians should engage in shared decision-making with patients, discussing both the benefits and risks associated with treatment options to enhance adherence and minimize adverse outcomes.

V. CONCLUSION

This study comprehensively examined adverse drug reactions (ADRs) associated with antihypertensive medications in the cardiology department of a tertiary care hospital. Key findings includeFurosemide (Lasix) emerged as the most common causative agent, implicated in 47.3% of ADRs, predominantly manifesting as hypotension, hypokalemia, and constipation.Using Naranjo's probability scale, the majority (71.1%) of ADRs were classified as probable, with no severe ADRs reported. Most ADRs were mild (65.8%), requiring minimal intervention.A higher incidence of ADRs

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was observed among patients aged 61-70 years, reflecting age-related susceptibility to medication effects.

Study Limitations: Despite its insights, this study has several limitations:
Conducted at a single tertiary care hospital, limiting generalizability to broader populations. The study involved a relatively small sample size over a short duration, which may not capture rare or long-term ADRs.

Competing Interests
The authors declare that they have no competing interests.

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