Pharmacovigilance: A Cross-Sectional Hospital Base Research Survey on Antihypertensive Drugs and their Adverse Drug Reaction

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Abstract-
Aim: The study's goals were to identify and document adverse drug reactions (ADRs) in adult male and female patients as well as elderly patients receiving antihypertensive medication treatment at the Super Speciality Hospital in Amravati.
Methods: Using in-patients at a Super Speciality Hospital, we conducted a three-month survey-based cross-sectional study. Patients were included based on predetermined criteria, and GraphPad Prism and Microsoft Excel 7 were used for data analysis.
Results: The study highlights how important it is to use drug usage and prescription pattern surveys to comprehend how medications affect society. It shows that during combination therapy for antihypertensive agents, there is a greater incidence of essential hypertension in men and a rise in adverse drug reactions (ADRs), particularly in women, such as sweating and weakness. Commonly administered antihypertensive telmisartan exhibits notable adverse drug reactions (ADRs), underscoring the need for customised treatment regimens and close observation in addition to blood pressure management. All things considered, the results offer insightful information for tailored treatment, illuminating the intricate dynamics of drug use and its effects.
Conclusion: To sum up, telmisartan has become the most often prescribed angiotensin II receptor blocker (ARB) within its respective category. Adverse drug reactions (ADRs) were notably more common in females, with frequent reports of headache, nausea, weakness, sweating, and dizziness. After analysing the demographic information, co-morbidities, use of ARBs, and the variety of ADRs linked to different ARBs in research participants, it was evident that improving ADR management and preventive measures can greatly improve treatment outcomes for patients.

Keywords: **Calcium Channel Blockers, Amlodipine, Metoprolol (Beta Blockers), Telmisartan-40 Mg, Angiotensin Receptor Blockers (ARBS), Antihypertensive Medications**.

INTRODUCTION

Pursuant to the World Health Organisation, pharmacovigilance is the science and tasks connected with recognising, evaluating, comprehending, and preventing harmful effects or any other concerns related to pharmaceuticals. Pharmacovigilance incorporates all of these aspects. The purpose of this definition is to limit the number of instances of excessive drug usage. Abuse of drugs, failures in therapy, and mistakes in the administration of drugs are all common, regardless of purpose. To achieve the greatest possible treatment results with medicines is an essential component of patient care, and it is an intrinsic part of the process. Effective pharmacovigilance plays a critical role in immediately identifying and managing risks after a medicine has been released onto the market. This is because side effects can be caused by a variety of reasons, even though the objective is to avoid causing harm to people using the medicine.[1]It is possible to divide adverse medication reactions into two distinct categories. Exaggerated expressions of the drug's usual pharmacology and toxicity are the hallmarks of type A responses, which are characterised by their frequency, predictability, and typically dose-dependent nature. The chance of mortality is rather low. On the other hand, type B reactions are uncommon, unpredictable, and frequently unrelated to dose. They typically emerge as aberrant manifestations of the drug's pharmacology or toxicology, and they are associated with greater rates of severe morbidity and fatality.The condition known as high blood pressure, sometimes known as hypertension, is a common problem that people face in their day-to-day lives, particularly in the early years of maturity and in later years of life.It is a serious medical condition that serves as a concerning signal for the mortality and morbidity linked with the health of the heart and blood vessels, despite the fact that it is not a sickness in and of itself.[3] An isolated systolic

hypertension, also known as ISH, was once considered to be a natural aspect of the ageing process and to have little to no clinical significance. Nevertheless, it is increasingly acknowledged as a significant determinant in determining cardiovascular risk among the elderly, surpassing the relevance of increased diastolic blood pressure (DBP) in this regard.In addition, telmisartan, which is a highly lipophilic angiotensin II receptor blocker (ARB), demonstrates an insurmountable binding to the AT1 receptor.The terminal elimination half-life of this substance is approximately twenty-four hours.Within the scope of the global initiative, which encompasses all non-communicable diseases, the goal is to achieve a decrease of twenty-five percent in the prevalence of hypertension by the year 2025.Angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), beta-blockers, calcium channel blockers, centrally acting drugs, diuretics, and vasodilators have all demonstrated high levels of efficacy in the management of hypertension, making them viable candidates for early pharmacological therapy.It is [8,9].

METHOD

In order to investigate the occurrence of adverse effects that are associated with the utilisation of Angiotensin I Receptor Blockers (ARBs) for the treatment of hypertension, the research makes use of a prospective and observational experimental design. For the purpose of computing a variety of metrics, data that has been documented in a specific format serves as the basis. The research was carried out in the Cardiology outpatient department (OPD) and the Non-communicable Disease (NCD) unit of Super Speciality Hospital Amravati, which is located in Shrikrishna Peth, Amravati, Maharashtra 444601. The study lasted for a period of three months, beginning in October 2023 and ending in January 2024. The protocol for the study, which included the collecting of data, was approved by the Institutional Ethics Committee in terms of following ethical standards. Interviews with patients will be conducted in the Cardiology department using a form that has been specifically developed, and informed consent will be obtained from the patients. All of the information that is gathered will be archived and maintained with confidentiality. For the purpose of the analysis, the data will be evaluated according to the "number of occurrences" (n) and the proportion (%).

RESULTS:

The characteristics that correspond to the demographics of the people that participated in the study:

Each of the fifty hypertensive patients who participated in the study was included for the entirety of the research project. Angiotensin Receptor Blockers, Calcium Channel Blockers, Beta Blockers, and combinations of these medications were prescribed to some of the patients in this group. Other individuals were given a combination of these medications. Fifty percent of the population was comprised of individuals between the ages of 51 and 60. Of the individuals that took part in the study, 27 (or 54%) were males, while 23 (or 46%) were females. There were 38% of people who smoked, whereas 62% of people did not smoke.

Table 1: Characteristics Pertaining to the Demographics of the Study Participants.

Characteristics	Number of occurrences(n)	Proportion (%)
Sex		
Male	27	54%
Female	23	46%
Age (Years)		
31-40	5	10%
41-50	8	16%
51-60	25	50%
61-70	7	14%
71-80	5	10%
Social Status		
Smokers	19	38%
Non- Smokers	31	62%

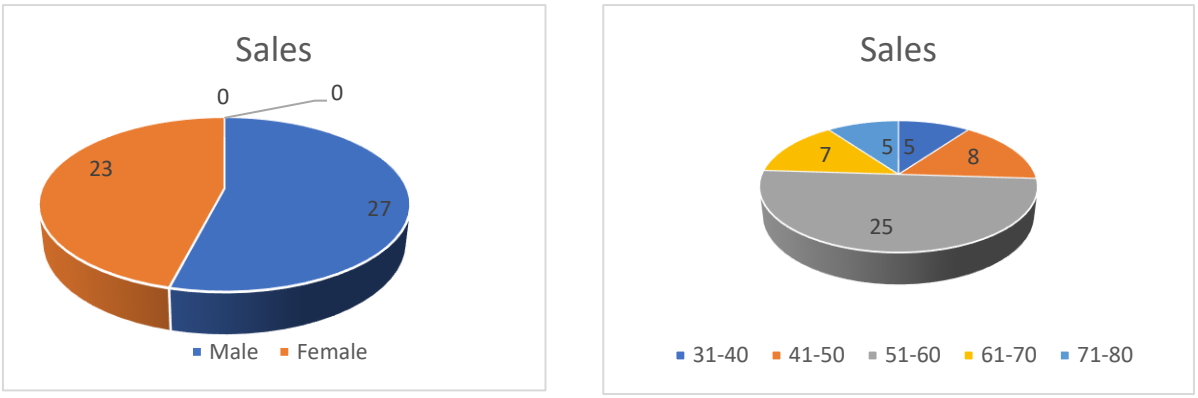

Figure 1: Ratio of Male and Female

ADVERSE DRUG REACTIONS (ADRS) IN BOTH MONOTHERAPY AND COMBINATION THERAPY:
The overall count of adverse drug reactions (ADRs) that were detected in the sample that was analysed is presented in Table 4. This includes information for both single-drug therapy and multi-drug therapy. The findings of the study showed that monotherapy had a much lower incidence of adverse drug reactions (ADRs), with a total of 19 (73%), in comparison to combination therapy, which had a total of 31 (77%).

Table 2: Classified According to Age

Sr. No	Medication therapy	Patient quantity	ADR count	Proportion (%)
1	Single drug therapy	19	14	73%
2	Multi-drug therapy	31	24	77%

EVALUATION OF ADVERSE DRUG REACTIONS (ADRS):
Our study identified various types of ADRs as follows.

Table 3: The Total Count of Adverse Drug Reactions (ADRS) In the Tested Sample Was Observed In both Single Drug Therapy and Multi-Drug Therapy.

Sr. No	Patient Details	Medicine	Adverse Drug Reaction
1	UM-62/F	Telma-40,Amlo-5mg,Calcium	Sweating,Weakness
2	ML-52/F	Telma-40,Clopidogrel,Aspirin	Dizziness
3	SM-76/M	Metoprolol,Aztor(statin),Ecosprin,Clopidogrel	No Effect
4	DW-35/M	Telma-40,Aten-50,Ecosprin,Atorvastatin,Nimesulide	Dizziness
5	NS-73/M	Telma-40,Amlodipine,Ecosprin	Headache
6	VK-60/M	Met XL,Atorvastatin,Sitagliptin,Ecosprin,Axcer-90	Dizziness
7	VM-53/M	Met XL,Atorva-40,Pan-40,Thyroxine,Methyl-Cobalamin	Headache
8	KG-38/F	Telma-40,Ecosprin,Sorbitrate	Sweating,Weakness
9	DS-52/M	Telma-40,Atorvastatin,Pan-40	Dizziness
10	MB-47/M	Telmisartan,Met XL,Pan-40	Hypoglycaemia
11	AN-59/M	Amlo-5,Sorbitrate,Ecosprin 75,Pan-40	Hyperacidity, Headache
12	CB-45/F	Micardis-20,Telmisartan,Calcium and Vitamin D	Headache
13	RY-59/M	Nifedipine,Pantoprazole	Hyperacidity
14	PB-35/M	Diltiazem, Pantoprazole	Dizziness
15	AD-72/M	Metformin, Telmisartan	Hypoglycaemia
16	AA-55/M	Metoprolol	Nausea
17	RG-70/M	Amlo 5mg	Nausea

18	GS-55/M	Telma-40mg, Amlo-5mg	Headache
19	PL-54/M	Telma-40mg	Nausea
20	GZ-53/M	Amlo-5mg	Dizziness
21	MY-68/F	Telma-40	Nausea
22	SM-60/F	Atenolol	Dizziness
23	KS-60/F	Amlo-5mg	sweating
24	RM-65/F	Amlo-5mg, Metformin	Nausea
25	DS-40/F	Telma-40mg, Amlo-5mg	Headache
26	RK-55/F	Telma-40, Metformin	Dizziness
27	TB-50/F	Telma-40, Metformin	Hypoglycaemia
28	SW-55/F	Thyroxine, Telma-40mg	Dizziness
29	AL-54/F	Telma-40mg	Nausea
30	SS-54/M	Metoprolol 25mg, Ecosprin	Nausea
31	VS-48/M	Telma-40 mg, Amlo-5mg	Sweating,Weakness
32	AP-48/F	Telma-40mg	Headache
33	ST-54/M	Metformin, Telmisartan	Nausea
34	SB-54/M	Telma-40mg	Headache
35	GG-49/M	Telma-40mg	Headache
36	AK-55/M	Telma-40mg	Nausea
37	SR-50/M	Amlo-5mg	Headache
38	AB-50/M	Telma-40mg	Nausea
39	SS-74/F	Telma-40mg, Metformin	Sweating,Weakness
40	KP-59/M	Telma-40mg	Dizziness
41	SI-57/M	Telma-40mg, Amlo-5mg	Nausea
42	MS-55/F	Telma-40mg	Dizziness
43	VG-60/F	Telma-40mg, Glimepiride	Nausea
44	AR-67/M	Metformin, Telmisartan, Ecosprin	Sweating,Weakness
45	SR-65/F	Amlodipine	Nausea
46	RM-50/F	Amlodipine	Hyperacidity
47	SK-35/F	Telma-40mg, Amlo-5mg	Headache
48	LP-45/F	Nicardipine	Sweating,Weakness
49	PP-65/F	Amlodipine-5mg, Atenolol	Sweating, Weakness
50	AP-70/F	Metformin, Telma-40mg	Sweating, Weakness, Hypoglycaemia

Adverse drug reactions (ADRs) caused by anti-hypertensive drugs:

The following table 6 presents the various forms of adverse drug reactions (ADRs) that were found to be associated with anti-hypertensive medications that were found in the sample that was examined. The following table provides an overview of the many outcomes that were achieved.

Table 4: Information on Adverse Drug Reactions Occurring in Hospitalized Patients.

Sr.No	Category of response	ADR count	Proportion (%)
1	Headache	9	18%
2	Sweating, Weakness	7	14%
3	Dizziness	11	22%
4	Nausea	13	26%
5	No Effect	10	20%

Indication, whether with or without co-morbidities:

The following categories were applied to a total of fifty patients who were receiving antihypertensive medication (ARBs), regardless of whether or not they displayed any co-morbidities: Sixty-six percent of patients have hypertension, eight percent have hyperlipidemia, eighteen percent have diabetes, four percent have hypothyroidism, and four percent have angina pectoris.

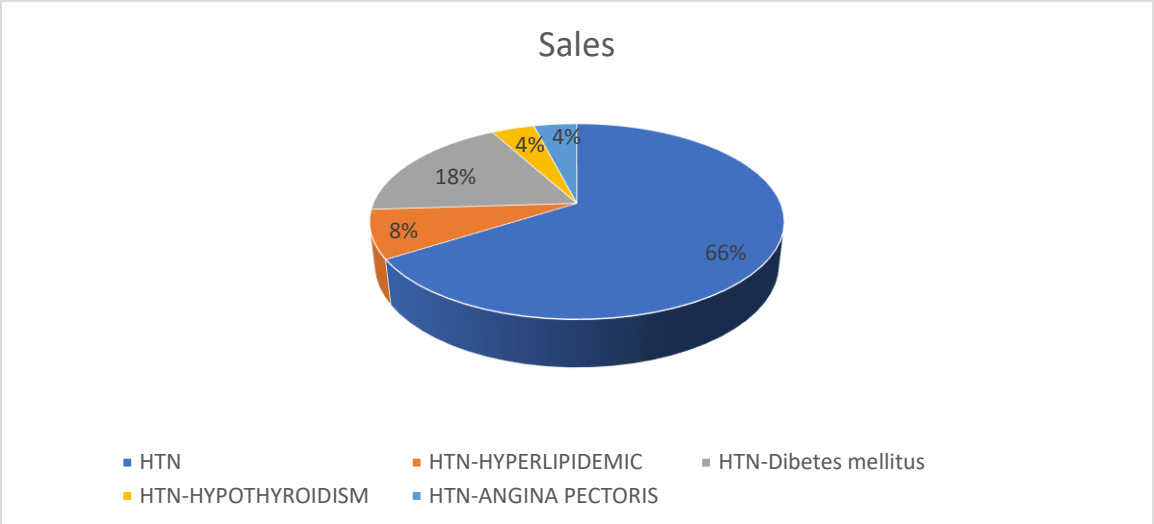

Figure 2: Indication With or Without Co-Morbidities

DISCUSSION:

Studies on drug utilisation, as defined by the World Health Organisation (WHO), include the marketing, distribution, prescription, and utilisation of medications in society, with an emphasis on the medical, social, and economic effects of these drugs. Within the realm of drug utilisation studies, prescription pattern surveys are an essential methodological instrument that provide a full understanding of the disease profiles of patients as well as the prescribing practices of practitioners.

The monitoring of adverse drug reactions (ADRs) is extremely important since these reactions not only have an impact on the patient's health but also have effects on the patient's finances. Our research is therefore centred on locating, reporting, and keeping track of adverse drug reactions (ADRs).

The gender distribution of the patients in a research study on pharmacovigilance revealed that 54% of the patients were male, whereas 46% of the patients reported being female. One of the findings of the study was that the prevalence of essential hypertension was much higher among males than it was among females. When compared to monotherapy, the likelihood of experiencing adverse drug reactions (ADRs) is higher when antihypertensive medications are combined. Perspiring and weakness were the most common adverse drug reactions that were found in females.

The use of multiple antihypertensive medications together results in a higher incidence of adverse drug reactions (ADRs) when compared to the use of a single medication. In females, the most common adverse drug reactions (ADRs) that are seen include perspiration and weakness. Additionally, throughout therapy, additional symptoms such as dizziness, headache, and nausea may additionally develop. Telmisartan, an antihypertensive medication that is frequently used, is frequently administered in conjunction with a variety of different medications, including but not limited to antacids and antiplatelets. Among the adverse drug reactions (ADRs) that can occur with Telmisartan treatment, it is noteworthy that 26% of patients experience nausea, 14% report sweating and weakness, 22% experience dizziness, 18% have headaches, and 20% do not experience any adverse drug reactions at all.Vasodilation is the mechanism by which telmisartan, which is categorised as an Angiotensin Receptor Blocker (ARB), exerts its high blood pressure-lowering effects. Within the context of the present management of hypertension, it stands out as a medication that is commonly prescribed. In addition, calcium channel blockers are useful in the treatment of mild cases of hypertension. In situations where a patient comes with both hypertension and diabetes mellitus, it is usual practice for physicians to prescribe telmisartan in conjunction with metformin for the purpose of providing comprehensive care.

The adverse drug reactions (ADRs) that have been documented in association with Telmisartan, particularly when it is used in combination therapy, highlight the significance of designing individualised treatment strategies and closely monitoring patients. Because of the wide variety of symptoms, which include nausea, sweating, weakness, dizziness, and headaches, it is essential for medical professionals to take into account the patient's general well-being in addition to controlling their blood pressure. The discussion on the classification of telmisartan as an angiotensin receptor blocker offers insight into the mode of action of the medication, which explains why it is so powerful in producing

vasodilation. Since calcium channel blockers are now recognised as an alternate therapeutic option for moderate hypertension, the range of treatment choices that are available has been expanded.
Some of the adverse drug reactions (ADRs) that are classified as Type A are sweating, weakness, dizziness, headache, and nausea. These reactions are also generally referred to as predictable reactions.These symptoms are typically associated with the known pharmacological effects of the medication, and they are depending on the dosage. They are experienced by a sizeable portion of the population that is taking the medication.
During the course of treatment with antihypertensive medication, hypersensitivity reactions could manifest themselves in the form of skin rashes and itching.

CONCLUSION:

In our comprehensive drug utilisation study, pharmacovigilance research and antihypertensive medication findings illuminate the complex landscape of medication use and its ramifications. Our research shows that prescription pattern surveys help identify illness profiles and prescribing behaviours.
The higher prevalence of essential hypertension in males and the higher frequency of adverse drug reactions (ADRs) in females, especially with combination medication, highlight gender-specific antihypertensive treatment. Telmisartan, a common ARB, caused nausea, sweating, weakness, dizziness, and headaches. Individualised treatment strategies and close monitoring are crucial.
Telmisartan's mode of action and ADRs shed light on antihypertensive therapy. Calcium Channel Blockers provide an alternative for moderate hypertension, and hypertensive diabetics are often prescribed Telmisartan with metformin. This shows the complexity of treatment decisions.
The predicted Type A Adverse Drug Reactions, related with recognised pharmacological actions, emphasise the necessity for healthcare practitioners to address side effects during therapy. Hypersensitivity reactions such skin rashes and itching emphasise the significance of detecting and controlling unanticipated antihypertensive drug effects.
Our findings emphasise the need for personalised, patient-centered antihypertensive therapy that includes careful monitoring, gender-specific variables, and ADR awareness. Optimising therapeutic outcomes and minimising drug use's medical, societal, and economic effects require this holistic approach.

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