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Post-Marketing Surveillance of Antihypertensive Drugs Based on Toxic Effects

Shweta S. Shirtode and Apeksha A. Gangurde
Students, Samarth College of Pharmacy, Belhe, Pune, Maharashtra, India

Abstract: *Pharmacovigilance is essential for monitoring and evaluating the safety of medications, especially regarding the long-term use of antihypertensive drugs. The goal of this study is to assess the toxic effects of different antihypertensive agents, with an emphasis on their adverse drug reactions (ADRs), and to identify patterns in the occurrence and intensity of these effects. A thorough analysis was performed using data obtained from clinical trials, post-marketing surveillance, and systems for reporting adverse events. The antihypertensive medications assessed include ACE inhibitors, angiotensin receptor blockers (ARBs), calcium channel blockers (CCBs), diuretics, and beta-blockers.*

The results show that some drug classes have greater risk profiles for common adverse consequences as electrolyte imbalances, renal failure, hypotension, and hyperkalaemia. For example, diuretics were linked to hypokalaemia and dehydration, whereas ACE inhibitors and ARBs were linked to a higher incidence of renal damage and hyperkalaemia. The study also looked at how drug interactions, comorbid illnesses, and patient demographics affect the incidence of adverse drug reactions.

This research underscores the importance of ongoing pharmacovigilance to detect and mitigate risks associated with antihypertensive therapies. It also emphasizes the need for personalized treatment approaches, regular monitoring, and timely reporting of adverse effects to optimize patient safety and improve clinical outcomes in the management of hypertension..

Keywords*:* Pharmacovigilance, Antihypertensive drugs, Adverse drug reactions (ADRs), Drug toxicity, Drug safety, Post-marketing surveillance, Adverse event reporting, Drug monitoring

I. INTRODUCTION

One of the most common chronic illnesses in the world, hypertension is a significant risk factor for cardiovascular morbidity and death. Long-term pharmacological treatment with antihypertensive medications, such as beta-blockers, calcium channel blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), and diuretics, is primarily responsible for managing hypertension. Long-term use of these drugs may result in a number of toxic effects and adverse drug reactions (ADRs), which can affect patient compliance, quality of life, and treatment results overall, even though they successfully lower blood pressure and avoid problems.

In order to identify, evaluate, comprehend, and avoid side effects or any other drug-related issues, pharmacovigilance is essential. Pharmacovigilance programs that continuously monitor the safety of antihypertensive drugs aid in the identification of adverse responses that were previously unknown, the assessment of their frequency and severity, and the assurance of safer therapeutic usage. Understanding the toxicity profile of antihypertensive drugs is crucial for prudent prescribing and reducing therapeutic risks because of their widespread and frequently lifetime usage.

Importance of pharmacovigilance:

Antihypertensive medications are among the most often prescribed pharmaceuticals worldwide, and hypertension necessitates lifelong management. These medications are linked to a variety of adverse drug reactions (ADRs), even though they successfully lower blood pressure and guard against problems including myocardial infarction and stroke. If not detected early, some of these harmful consequences, like electrolyte imbalances, renal impairment, hepatotoxicity, or severe allergic reactions, can be dangerous and even fatal.

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Therefore, pharmacovigilance is crucial to guaranteeing the safe and efficient administration of antihypertensive medication. Ongoing ADR monitoring aids in the identification of hitherto unknown toxicities, comprehension of their processes, and assessment of their prevalence in practical contexts. Additionally, it offers useful information that helps medical professionals make well-informed clinical decisions, modify treatment plans, and notify patients about potential adverse effects.

This study is significant because it helps identify toxicity patterns and safety indicators linked to various antihypertensive medication groups. The results have the potential to enhance post-marketing medication surveillance systems, lower the likelihood of unfavorable outcomes, and improve prescribing practices. In the end, pharmacovigilance research such as this one is essential for improving patient safety and managing hypertension more effectively overall.

In conclusion, a set of pharmacovigilance-focused metrics will:

help ensure the ongoing safety and effectiveness of antihypertensive medications by methodically identifying, evaluating, and preventing adverse drug events. These indicators will track drug toxicity trends, pinpoint risk variables, and assess the results of clinical or regulatory actions. Healthcare practitioners can strengthen post-marketing surveillance systems, increase patient safety, and prescribe better medications by evaluating such data. In the end, these factors support the prudent use of antihypertensive drugs and help create a safer healthcare environment.

Need of pharmacovigilance :

Pharmacovigilance plays a crucial role in ensuring the safe and effective use of antihypertensive drugs. Since these medications are prescribed for long-term management of hypertension, patients are at continuous risk of developing adverse drug reactions (ADRs) such as electrolyte imbalance, renal dysfunction, cough, dizziness, and hypotension. Some antihypertensive agents, like ACE inhibitors, beta-blockers, and calcium channel blockers, may produce toxic effects that vary depending on patient age, comorbidities, and drug interactions. Therefore, systematic monitoring and reporting of such adverse effects through pharmacovigilance programs are essential to identify new safety signals, minimize risks, and improve patient outcomes. The need for pharmacovigilance arises not only to ensure patient safety but also to guide healthcare professionals in rational prescribing and policy-making based on evidence from real-world data.

To guarantee the safe and efficient use of antihypertensive medications, pharmacovigilance is crucial. These drugs are frequently taken for extended periods of time, which raises the possibility of harmful side effects such liver damage, hypotension, dizziness, renal impairment, and electrolyte imbalance. Serious complications are avoided and toxicities are detected early with the use of ongoing monitoring of adverse medication reactions. Pharmacovigilance is necessary to detect uncommon or unexpected side events, increase patient safety, and improve treatment quality. Additionally, it gives regulatory agencies and medical practitioners useful information for revising treatment protocols and guaranteeing the prudent use of medications. All things considered, pharmacovigilance is essential for patient safety and preserving trust in antihypertensive medication.

Significance of pharmacovigilance:

In order to address the issues brought on by the growing diversity and potency of pharmaceuticals, particularly the unpredictability of vitamin hazards, pharmacovigilance—a developing clinical and scientific field—is crucial. It is crucial that negative impacts and toxicities—especially those that have not yet been identified—be reported, examined, and their ramifications clearly conveyed to a knowledgeable audience that can decipher the information. All drugs have an inherent trade-off between the possibility of negative side effects and their benefits. By making sure that high-quality, safe, and effective medications are used rationally and taking patients' expectations and concerns into account when making therapeutic decisions, this risk can be reduced. Pharmacovigilance's goals include: promoting public health and encouraging patient trust in the drugs they take, which in turn boosts confidence in the health service as a whole; anticipating and managing drug use risks; providing regulators with crucial data to update medication use recommendations; improving public-health professional communication; and educating healthcare providers about the risks and efficacy of the drugs they prescribe.

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This emphasizes how important pharmacovigilance is.

The National Drug Policy is one of the main areas where pharmacovigilance is integrated. Establishing drug regulatory bodies with strong pharmacovigilance programs is the first step in any country to ensure the safety and responsible use of pharmaceuticals. These programs are crucial for tracking and assessing adverse medication responses as well as for efficiently informing relevant stakeholders of findings. Pharmacovigilance programs allow medical practitioners to be informed and up to date on the side effects of pharmaceuticals in clinical practice. Poorly designed healthcare systems and a high prevalence of tropical infectious diseases, which frequently strike the same population at the same time, provide problems for many emerging and undeveloped nations.

As a result, it is common in these areas to administer several medications without giving enough thought to possible negative drug responses or interactions. Pharmacovigilance programs in these situations require thorough training for medical personnel, which raises general awareness of safe drug use. Many national and international organizations provide useful data and recommendations for the efficient execution of pharmacovigilance initiatives around the world. These organizations are great tools for controlling the dangers associated with drug use. The importance of pharmacovigilance as a key instrument for guaranteeing pharmaceutical safety in public health is highlighted by the World Health Organization's (WHO) comprehensive database, which offers crucial information on its successful application.

History of pharmacovigilance:

The Greek word "Pharmakon," which means "drug," and the Latin word "vigilance," which means "to keep watch," are the roots of the term "pharmacovigilance."

Pharmacovigilance's beginnings date back 169 years to January 29, 1848, when a little girl from northern England named Hannah Greener sadly died after receiving chloroform anesthesia before having an infected toenail removed. Chloroform was first recognized by Sir James Simpson as a safer and more efficient anesthetic, and he later adopted it into medical practice. The circumstances surrounding Hannah's death were investigated, but the precise cause was never determined. She most likely died from pulmonary aspiration or a deadly arrhythmia.

1. Thalidomide Tragedy (1950s–1960s): Originally sold as a sedative and antiemetic, Thalidomide caused serious congenital impairments in a large number of newborns. This catastrophe made clear how urgently drug safety has to be systematically monitored. The fallout from this incident raised awareness of the possible dangers of medications, especially during pregnancy.

2. Creation of WHO Program (1968): The World Health Organization (WHO) established the International Drug Monitoring Program in 1968 following the thalidomide catastrophe.

By encouraging cooperation in the gathering and examination of data pertaining to adverse drug reactions (ADRs), this program laid the foundation for a global network of pharmacovigilance centers.

3. The Adverse Event Reporting System (AERS) was first implemented by the Food and Drug Administration (FDA) in the 1970s. In order for the FDA to monitor and control drug safety in the US, AERS became a crucial tool for collecting, organizing, and evaluating data on adverse events connected to pharmaceuticals.

4. The 1990s ICH Guidelines: The global standardization of pharmacovigilance procedures was greatly aided by the International Conference on Harmonization (ICH). By creating a uniform framework for the gathering and exchange of safety data, ICH guidelines—including E2B—improved regulatory agencies' ability to work together internationally.

5. EU Pharmacovigilance System (2005): To strengthen the monitoring and supervision of pharmaceuticals, the European Union established a thorough pharmacovigilance system. Coordination of safety evaluations and risk management plans was greatly aided by the European Medicines Agency (EMA).

6. Periodic Safety Update Reports, or PSURs: These reports are now required for those with marketing authorizations. Regular reporting of safety data to regulatory bodies is required for these reports, which guarantee continuous assessment of a drug's safety profile over the course of its lifecycle.

7. Digital Era and Signal Detection (21st Century): Pharmacovigilance procedures have changed as a result of technology, which makes data analysis and signal detection more effective.

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8. International cooperation is a top priority in modern pharmacovigilance. Programs like the WHO's global individual case safety reports (ICSRs) platform encourage consistent reporting and international information sharing. In order to oversee and guarantee the safety of pharmaceutical goods, this collaborative approach involves patients, pharmaceutical companies, regulatory agencies, and medical professionals.

9. On June 30, 1906, the United States Federal Food and Drug Act was passed, requiring that medications be pure and unadulterated. This body also outlawed the fabrication of pharmaceutical medicinal claims in 1911.

Sulfanilamide elixir, which used diethyl glycol as its solvent, was responsible for 107 deaths in the United States in 1937. Although the manufacturing business was not aware of this solvent's harmful characteristics at the time, it was determined to be the cause of the deaths.

Due to the Thalidomide tragedy, European Pharmacovigilance underwent a dramatic change in 1961. In a letter to the editor of the Lancet Journal, Australian doctor Dr. McBride suggested a connection between thalidomide and congenital birth defects. He pointed out that among women who had taken thalidomide during their pregnancies, the percentage of newborns born with congenital abnormalities increased from 1.5% to 20%. Following extensive animal research, Thalidomide was first promoted as a sedative and made available as an over-the-counter (OTC) drug. In the late 1950s and early 1960s, pregnant women all over the world began using it extensively to help with morning sickness.

Pharmacovigilance was first implemented in India in 1986. Though a formal Adverse Drug Reactions (ADR) monitoring system was established, with 12 regional centers serving 50 million people each, there was no increase. India took part in the Uppsala, Sweden-based World Health Organization's (WHO) ADR monitoring program in 1997, however this endeavor was a failure. As a result, after 2005, India's National Pharmacovigilance Programme (NPPV), which is supported by the WHO and funded by the World Bank, became live. In 1898, the commercialization of diacetylmorphine—later renamed heroin—became a major problem, and by the early 1900s, addiction had spread widely.

Approximately 0.5 million people were found to be dependent on this chemical in the United States alone. Thalidomide was first made available as an over-the-counter hypnotic and sedative in 1957. It was later administered to pregnant women to treat their nausea. This was confirmed the following year when it was found that 20% of the phocomelia and limb agenesis cases that were reported were caused by thalidomide.

What is mean by hypertension:

The World Health Organization (WHO) has identified hypertension as a leading cause of illness and mortality worldwide, contributing to over nine million deaths annually. High blood pressure, also known as hypertension, is defined by the National Institute for Health and Care Excellence (NICE) in the United Kingdom as a clinical blood pressure reading of 140/90 mmHg or higher, which needs to be verified by a subsequent average of 135/85 mmHg or higher from ambulatory blood pressure monitoring during the day (or from home blood pressure monitoring).

An excessive rise in either the diastolic or systolic blood pressure is the hallmark of hypertension; although mean arterial pressure is also raised, it is rarely observed in humans.

In the past, diastolic measurements were given more weight for diagnosing hypertension.

However, it is now known that a higher risk of coronary and cerebrovascular disorders, including stroke, is associated with elevated systolic pressure, sometimes known as "systolic hypertension."

As a result, systolic and diastolic pressures are now regarded as important in clinical evaluations.

It's crucial to remember that high blood pressure is not just a problem for older folks; in England, over 2.1 million people under 45 were estimated to have it in 2015.

Nowadays, routine or opportunistic blood pressure checks performed in primary care settings are the main way that medical professionals detect hypertension. One worldwide risk factor for the burden of cardiovascular disease and its related mortality is hypertension.

It is frequently connected to a number of harmful habits, such as smoking, eating poorly, being obese, drinking too much alcohol, not exercising, and leading sedentary work lives.

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Furthermore, a person's perspective and understanding of their hypertension are important factors in encouraging lifestyle modifications and the adoption of healthy habits.

According to the 2017 ACC/AHA guideline definition (blood pressure ≥130/80 mmHg), the prevalence of hypertension among adults in the US has increased to 45.6% from 31.9% based on the previous criteria (blood pressure ≥140/90 mmHg). A chronic rise in blood pressure is known as hypertension, and it is linked to increased rates of morbidity and the potential for long-term harm to important organs.

History of Hypertension:

The history of hypertension dates back thousands of years. Ancient physicians such as Hippocrates and Galen described symptoms resembling high blood pressure, though they lacked accurate diagnostic tools. The real understanding of hypertension began in the 18th century, when Stephen Hales (1733) first measured blood pressure in animals using a glass tube inserted into an artery. Later, in the 19th century, advances by scientists like Riva-Rocci (1896), who invented the mercury sphygmomanometer, and Korotkoff (1905), who discovered the Korotkoff sounds used to measure blood pressure, made it possible to measure human blood pressure accurately.

The term “essential hypertension” was introduced in the early 20th century to describe high blood pressure without an identifiable cause. Over time, with growing medical research, hypertension was recognized as a major risk factor for cardiovascular diseases, including heart attack and stroke. The development of antihypertensive drugs in the mid-20th century—such as diuretics, beta-blockers, ACE inhibitors, and calcium channel blockers—marked a turning point in the effective management of the condition. Today, hypertension is one of the most studied chronic diseases worldwide due to its high prevalence and impact on global health.

Common prescribed medicine for anti-hypertension:

Many antihypertensive drugs are used to treat hypertension; the following classes are strongly advised for first treatment:

1. Thiazide-type diuretics
2. Calcium channel blockers
3. Angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs)
4. Alpha blocker
5. Beta blocker

Thiazide Diuretics:

Typically, thiazide and thiazide-like diuretics are used to treat hypertension. According to JNC8 guidelines, thiazide diuretics, either by themselves or in conjunction with other antihypertensives, can be used as the first line of treatment for hypertonic hypertension (HTN) in individuals of all ages and races, unless there is evidence of chronic kidney disease, in which case an angiotensin-converting enzyme inhibitor or an angiotensin II receptor blocker is prescribed. Thiazide diuretics were recommended as the first line of treatment for hypertension by the ALLHAT Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial, barring contraindications. Treatment with hydrochlorothiazide at doses of 12.5 mg or 25 mg per day has not been found to lower morbidity or death when used alone.

Calcium Channel Blockers CCBs:

Similar to the effects of thiazide diuretics, calcium channel blockers (CCBs) have been shown to reduce all cardiovascular outcomes except heart failure. For patients who cannot tolerate thiazides, they are the best substitute product.

The two main classes of calcium channel blockers (CCBs) are dihydropyridines and non-dihydropyridines. Dihydropyridines are mostly used to treat hypertension because of their increased effectiveness as vasodilators. They are especially well-suited for controlling excessive blood pressure since they have little effect on cardiac contractility and conduction. Among the most often prescribed drugs in this class are nifedipine and amlodipine. Non-

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dihydropyridines, on the other hand, have stronger effects on cardiac conduction and contractility but are less effective vasodilators. As a result, they are used more often as antiarrhythmic drugs than to manage high blood pressure.

ACE inhibitors and ARBs:
The recommended antihypertensive medications for people with heart failure and chronic renal disease are ACE inhibitors and angiotensin receptor blockers (ARBs). For individuals with chronic renal disease who show symptoms of proteinuria, these drugs are advised as the first line of treatment. It has been demonstrated that thiazide diuretics are superior to ACE inhibitors in lowering blood pressure and preventing strokes, whereas calcium channel blockers (CCBs) are superior to ACE inhibitors in lowering blood pressure and preventing heart failure and strokes.

Alpha-blockers:
Because alpha blockers are less effective than other first-line medications at preventing cardiovascular disease, they are not advised as a first-line treatment for hypertension.

Beta-blockers:
Side effects include bradycardia, constipation, melancholy, exhaustion, and sexual dysfunction are frequently linked to beta-blockers. Additionally, these drugs may worsen peripheral vascular disease symptoms and cause bronchospasm. They may also cause Raynaud's syndrome to flare up.

ADR of that medication:
Thiazides Side Effects:
Numerous negative side effects are associated with thiazides and thiazide-like diuretics. Most of these side effects are directly related to the diuretic's dosage; the most common metabolic abnormalities are hypokalemia and hyponatremia, which are followed by hyperuricemia, hypomagnesemia, hyperlipidemia, and high glucose levels.

Calcium channel blockers:
When dihydropyridine calcium channel blockers (CCBs) are used, peripheral edema is often the result. Compared to amlodipine, long-acting nifedipine causes edema more frequently; this edema is dose-dependent with respect to the CCB. It is crucial to remember that this illness is neither linked to fluid or sodium retention nor a sign that heart failure is about to emerge.

ACE inhibitors :
A common side effect of ACE medications is moderate hyperkalemia. Even people with good kidney function are more likely to have hyperkalemia if they have diabetes, congestive heart failure, or renal failure. The incidence of syncope, acute renal damage, and hyperkalemia is similar for telmisartan and ramipril. However, a higher incidence of symptomatic hypotension is linked to telmisartan.

Alpha- blockers:
Because alpha-blockers dilate veins, they are associated with orthostatic hypotension and tachycardia.

Beta blockers:
Side effects include bradycardia, constipation, melancholy, exhaustion, and sexual dysfunction are frequently linked to beta-blockers. Additionally, these drugs may worsen peripheral vascular disease symptoms and cause bronchospasm. They may also cause Raynaud's syndrome to flare up.

II. CONCLUSION

Pharmacovigilance plays a critical role in ensuring the safety and efficacy of antihypertensive medications. The review of available literature and studies highlights that while antihypertensive drugs effectively control blood pressure and

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reduce cardiovascular risk, they are also associated with a range of adverse drug reactions (ADRs), including hypotension, dizziness, cough, peripheral edema, and electrolyte imbalances. Certain drug classes, such as beta-blockers and combination therapies, show higher incidences of ADRs, underscoring the importance of careful monitoring and individualized therapy.

Continuous monitoring, reporting, and assessment of ADRs are essential to optimize patient safety, improve treatment compliance, and inform clinicians' therapeutic decisions. Incorporating pharmacovigilance data into clinical practice allows healthcare providers to minimize toxic effects, enhance drug selection, and ultimately achieve better outcomes for patients with hypertension.

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