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Original Research Article

A Prospective Observational Study of Asthma Medication Utilization Patterns, Dosage Forms, and Adverse Drug Reactions in a Tertiary Care Hospital

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Abstract

Background: A chronic inflammatory disease of the airways, asthma affects almost 300 million people worldwide and is a major health concern. Patients with asthma who visited a tertiary care hospital were the subjects of this prospective observational pharmacovigilance research, which sought to investigate medication consumption trends, adverse drug reactions (ADRs), and the severity of these responses.

Aims and Objectives: (1) To evaluate and analyse the utilization patterns of asthma medication. (2) To analyse the different dosage forms used in asthma medication.

Material and Methods: Over the period of twelve months, 150 patients with bronchial asthma, ranging in age from 18 to 70 years, were registered and followed up with utilising standardised questionnaires.

Research Methodology: An analysis was conducted on demographic data, prescription schedules, and adverse drug reactions (ADRs). The Naranjo scale was used to measure causality, and the Modified Hartwig and Siegel scale was used to evaluate severity.

Results: The results showed that most patients used combinations of drugs, often two-drug regimens, with the most common medications being β2-agonists, corticosteroids, and methylxanthines. Inhalers were the second most popular type of dosing, behind tablets. Improving patient outcomes is the primary goal of this research, which emphasises the crucial importance of individualised treatments and the need for personalised treatment regimens to optimise asthma control while minimising ADRs.

Statistical Analysis: After data was input into an Excel spreadsheet, suitable tests were used for data analysis.

Keywords: Asthma, Adverse Drug Reactions, Pharmacovigilance, Causality Assessment, Medication Patterns.

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Introduction

Bronchial asthma is a chronic inflammatory illness of the respiratory tract that often results in hypoxia and difficulty breathing.[1] Bronchial asthma is caused by the contraction of smooth muscle and airway smooth muscle, which results in bronchial hyper-reactivity and airflow restriction. The activation of mast cells, the invasion of eosinophils and T helper 2 (TH2) lymphocytes, the production of IgE by B lymphocytes, and the release of numerous inflammatory mediators, chemokines, and growth factors by the airway epithelium are all variables that contribute to the pathophysiology of asthma.[2] People who suffer from asthma have a delayed response to allergens, experiencing bronchoconstriction anywhere from eight to twenty-four hours after being exposed to the allergen. In the latter stages, the airways become hypersensitive to stimuli that are not particular to them, and inflammatory cells flow into the airways.[3]

The condition known as asthma, in addition to being one of the primary causes of sickness in children, has the potential to cause psychological disturbances within families. On average, between seven and ten percent of females and between ten and fifteen percent of boys are diagnosed with asthma throughout their youth. Although it is more prevalent in men before to puberty, the incidence

starts to level off for females when they reach puberty.[4] Approximately 300 million individuals throughout the world are affected by asthma, and the prevalence of the condition is growing, especially among younger people. It is estimated that asthma will be responsible for 15 million disability-adjusted life years (DALYs).[5] Asthma-related causes of death account for 2,50,000 deaths worldwide. The number of hospitalizations that are a direct consequence of asthma is around 500,000 every year, with 34.6% of those patients being under the age of 18.[6]

The costs associated with asthma amount to close to $6.2 billion annually. The emergency department is visited by about 1.81 million individuals annually, which accounts for 47.8 percent of the total population.[7] The pharmaceutical therapy that takes care of both phases is considered to be adequate. A significant amount of financial and social strain is placed on families as a result of the fact that establishing clinical control of asthma often requires long-term treatment and active engagement from the patient. In the realm of asthma medication, the Global Initiative for Asthma (GINA) has provided recommendations that encompass β2 agonists, such as salbutamol, salmeterol, and formoterol; corticosteroids, such as fluticasone, prednisolone, and budesonide; xanthine derivatives, such as theophylline; leukotriene receptor antagonists, such as montelukast; antihistamines, mucolytics, and mast cell stabilizers. Each of these drugs may be used on its own, or they can be combined with other asthma treatments

Additionally, asthma in children and teenagers (ages 5–17) is directly responsible for the loss of school days amounting to $10 million and the payment of $726.1 million in expenditures to caregivers.[8] There is a significant lack of research conducted in India about the epidemiology of asthma. A study that was conducted more than three decades ago identified a frequency of 2.78 percent among urban individuals aged 30 to 49. The cost-effectiveness of various treatment options is a major problem due to the fact that asthma is a chronic condition that requires a significant number of medical resources. Utilizing this point of view, the study was designed. The objective of the researchers was to gather data on the patterns of medication usage among asthma patients who were pediatric and to conduct assessments of adverse drug effects.

In asthma, a chronic inflammatory condition of the airway, a reversible kind of airway blockage may arise either spontaneously or as a consequence of treatment. This blockage may result in a variety of symptoms. It has been suggested that the Greek origin of the term "asthma" refers to a condition defined by short breath. "a condition of the airways that causes them to narrow excessively in response to allergen or provoking stimuli that normally have no such effect"[9] is the perfect method to describe airway hypersensitivity. Airways in the lungs of asthmatic patients are orchestrated by a multitude of cell types, including mast cells, eosinophils, macrophages, CD4+ T lymphocytes, and epithelial cells. By over releasing pro inflammatory mediators, these cells become hypersensitive when they are exposed to allergens, pollutants, pollens, dust, or mites. This causes bronchoconstriction and inflammation of the bronchial passages. These abnormalities might appear clinically in a variety of ways, including recurrent wheezing, dyspnea, chest tightness, and pneumonia. Primary respiratory diseases are responsible for a significant amount of death and morbidity when they occur.

Asthma affects an estimated 300 million people throughout the world, and the number of people living with the condition is increasing at a pace of fifty percent per decade. Emerging countries are also experiencing frighteningly high asthma rates, perhaps as a consequence of increased urbanization. This is despite the fact that industrialized (westernized) nations have the highest asthma rates at the moment. Every year, asthma-related causes claim the lives of 250,000

individuals throughout the world, and the condition is responsible for the loss of 15 million disability-adjusted life years (DALYs). Asthma was at the 25th spot on the worldwide list of days missed due to sickness in the year 2001. Around five million children are affected by asthma, which is now believed to have a prevalence of between six and seven and a half percent. Children, it is the fourth most common cause of impairment and a common reason for students to skip school. It was estimated that the direct and indirect expenses of asthma in the United States amounted to $19.7 billion in 2007.[10]

Medical expenses and hospitalizations are examples of direct costs, whereas lost workdays and premature deaths are examples of indirect costs. Direct costs include hospitalizations and prescription expenses. Asthma episodes that are severe still result in the deaths of around 4,000 people in India each year.[11] This is despite the fact that there are several ideas and treatments available. One of the most significant financial burdens that asthma places on healthcare systems and governments is asthma. It has been shown that the primary etiologic reasons of asthma include bronchial hyper reactivity (BHR) to a variety of stimuli, including as dust, pollen, animal dander, and food, in addition to acute and chronic inflammation of the airways. A two-stage reaction is triggered in hypersensitive persons when they are exposed to allergens.[12] The first phase is characterized by inflammation, and the second phase is characterized by a late-phase reaction. Tolerance to inhaled provoking antigens is the first step in the creation of an airway immune response. This tolerance then causes sensitized Th0 cells to produce interleukins IL-4 and IL-5, which in turn cause Th2-type cells to become hypersensitive. The outcome is the creation of allergen-specific IgE, which binds to FCER1 receptors on the surface of mast cells. These receptors are high-affinity IgE receptors.

The excessive release of pro-inflammatory mediators like TNF-α and ILs is the causal factor behind the contraction of smooth muscle in the airways, edema, hyperplasia of goblet cells, mucus formation and clogging, and vasodilatation. Plasma is exuded into the airways as a consequence of microvascular leakage, which is caused by inflammatory mediators, as stated. Because of the acute leaking of plasma proteins, the wall of the airway becomes thick and inflated, and as a result, the lumen of the airway becomes smaller. If there are plasma exudates present in the lumen, it is possible that mucus clearance may be impeded, as stated in response to the direct stimulation of sub-epithelial vagal (parasympathetic) receptors, discovered that both central and local reflexes lead to the constriction of airways.[13] These changes in response to an allergen are referred to as an acute or immediate reaction, and they occur within a short period of time. Eosinophils are not the only leukocytes that are entrained by the additional cytokines that are generated by mast cells.

Other leukocytes, such as neutrophils and mononuclear cells, are also entrained by mast cells. It is these inflammatory cells that are responsible for initiating the late-phase response, which starts four to eight hours later and may extend anywhere from twelve to twenty-four hours or even longer. Eosinophils secrete mediators such as eosinophil cationic protein (ECP) and major basic protein (MBP), in addition to eosinophil peroxidase (EPO). These mediators are responsible for causing damage to the epithelial cells that line the airways and into other organs. Active eosinophils create leukotrienes, notably LTC4, which function to constrict airways. It is possible for eosinophils and Th2 cells to sustain and even amplify the inflammatory response if they are not exposed to the antigen that causes it. Dyspnea, wheezing, coughing, and chest tightness are all symptoms that are associated with an exacerbation, which is a condition that is brought on by an increase in inflammation.

In accordance with the findings anti-asthmatic medications can be classified into two distinct categories quick relief agents, which encompass short-acting inhaled β2 agonists, anti-cholinergic, and short-term systemic corticosteroids; and long-term control agents, which encompass inhaled and systemic corticosteroids, long-acting β2 agonists, methylxanthines, mast cell stabilizers, and leukotriene modifier medications.[14]

Corticosteroids are the most effective in terms of asthma treatment when it comes to anti-inflammatory drugs. Systemic corticosteroids are more often used for sudden episodes of asthma, while inhaled corticosteroids (ICS) are the way to go for long-term care of chronic asthma. Inhaled corticosteroids are the way to go? the most common adverse reactions that may occur as a result of long-term use of intracoronary steroids (ICS) are adrenal insufficiency and suppression of the hypothalamic-adrenal axis, decreased bone mineral density, cataracts, dysphonia, easy bruising, growth retardation, and impaired bone formation. Due to the fact that they do not inhibit the late phase inflammatory response or prevent a subsequent increase in bronchial hyperreactivity, β2 adrenergic agonists are the most effective and safest bronchodilators.

However, their primary purpose is to provide relief from symptoms. Tachycardia, skeletal muscle tremor, hypokalemia, and prolongation of the QTc interval are the most common adverse effects of these medications. These adverse effects may occur

when these medications are taken in excess or for an extended period of time. Formulations of sustained-release theophylline have been developed in an effort to treat nocturnal asthma. According to several adverse effects of theophylline include convulsions and abnormal heartbeats. These are among the most hazardous side effects. As a second-line therapeutic option, mast cell stabilizers such cromolyn sodium and nedocromil shouldn't be utilized until the patient has significant persistent asthma. Leukotrienes modifiers, such as zileuton, zafirlukast, and montelukast, are used to treat asthma that is mild enough to be persistent. [15]

When it comes to preventing or treating disorders like asthma, complementary and alternative medicine encompasses a wide range of practices, from the very modern to those with deep roots in traditional medicine. In the US, supplementary treatments have been used by as many as 41% of asthma patients. According to a study conducted by the National Asthma Campaign in the USA, it was discovered that 70% of severe asthma patients and 60% of moderate asthma patients utilize CAM. Acupuncture, aromatherapy, homoeopathy, reflexology, phytotherapy, chiropractic, and osteopathy are among the most common alternative therapies for asthma. Breathing exercises (including yoga), herbal remedies, acupuncture, and homoeopathy are among the most often used treatments.

When a person takes a medication, they run the risk of experiencing adverse drug reactions (ADRs), which are side effects that are undesired and sometimes even harmful. The severity of these effects may range from mild to severe, depending on the individual, the medication, and an assortment of other factors. Due to the fact that they may result in disease, incapacity, or even death [16] adverse drug reactions (ADRs) are a significant problem in the field of public health.

It is of the highest significance for healthcare practitioners to be aware of the risk of adverse drug reactions (ADRs) and to routinely monitor patients for signs of ADRs while they are under their care. Early detection and treatment of adverse drug reactions (ADRs) may help reduce the severity of the effects on patients and prevent more serious complications from occurring.[17]

Additionally, it is essential to record adverse drug reactions (ADRs) in order to find new or previously unknown medication hazards. This data might be used to amend the labels of medications, provide direction for the processes involved in the prescription process, and ultimately improve the safety of patients. Additionally, patients may assist in the management of adverse drug responses by promptly informing their physician of any peculiar or unanticipated side effects that they experience as a result of their prescribed medication.

Drug toxicity has an impact on the overall health of patients as well as the costs associated with medical treatment on a worldwide scale. In response to this issue, the World Health Organization (WHO) initiated a worldwide drug monitoring initiative with the goal of locating and removing medications that might be harmful to human health. Over the course of its trial study in 1968, which included participation from eleven nations, this program has seen significant development.

The effort, which is now being carried out in 86 countries and is managed by the World Health Organization and a cooperating center located in Uppsala, Sweden, is currently in operation. [18]

Testing for adverse drug reactions (ADRs) did begin at the same time as an effort was made to establish a countrywide monitoring program in India, which was around twenty years ago. One of the components of these activities was the development of five centres focused on providing assistance to ADR nurses. In Uppsala, Sweden, the National Pharmacovigilance (PV) Centre and the WHO Collaborating Centre for ADR Observing are both headquartered in the Department of Pharmacology at the All-India Institute of Medical Sciences in New Delhi. Both of these centres are located in Sweden.

Even though there are processes in place for voluntary reporting of adverse medication reactions, there is still a significant issue in India with the underreporting of these responses. The answer to this issue is to allow for spontaneous reporting that is prompt. The reporting of suspected adverse drug reactions by clinicians is a system that depends on the efforts of medical residents, chemists, or nurses to exert pressure on medical professionals.

By using prompts for spontaneous reporting, healthcare professionals may be encouraged to actively engage in the checking process and enhance their awareness of the significance of reporting adverse drug reactions (ADRs). This may be accomplished by communicating the importance of reporting ADRs. Additionally, it is advised that medical residents, chemists, and nurses be included in the reporting process in order to achieve the goal of increasing the total reporting rate. This increases the number of workers who are responsible for locating and reporting adverse drug reactions (ADRs).

Enhancing the monitoring and reporting of adverse drug reactions (ADRs) is really necessary in order to get comprehensive and precise information about the safety of medications that are used in India. These specifics are essential for identifying potential risks, determining the relative merits of

various medications, and determining the appropriate actions to take in order to keep patients safer.

From the perspective of the World Health Organization (WHO), an adverse drug response (ADR) is defined as any adverse reaction to a medication that takes place at levels that are typically used for the purpose of preventing, diagnosing, treating, or altering physiological function. These adverse effects, which are defined in this context as those that are unrelated to the therapeutic value of the therapy, may apply to any form of medication, regardless of whether it is prescription, available over-the-counter, herbal, or supplementary.

The WHO and the JCAHO have reached a consensus about the definition of adverse drug reactions (ADRs). A pharmacological response that either increases toxicity, diminishes the predicted therapeutic benefits, or does both is what the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) defines as an adverse drug reaction (ADR). This definition encompasses any unintended side effect of a medication that manifests itself at dosages that are employed for the purpose of diagnosis, therapy, prevention, or the modification of physiological systems. Both unpleasant and unanticipated side effects are covered in this description.[19]However, it is essential to bear in mind that the criteria and definitions of what constitutes an alternative dispute resolution (ADR) may differ somewhat from one organization or regulatory body to another. The adverse drug reactions (ADRs) that have been described here all have a single characteristic: they are responses to drugs that are both harmful and unexpected. On the other hand, serious adverse drug reactions (ADRs) result in significant injuries or need medical intervention in order to prevent long-term harm. It is only via the reporting of adverse drug responses (ADRs) and significant adverse drug events (ADEs) that medical professionals can make medications safer and ensure the safety of patients. An adverse drug reaction, also known as an ADR, is defined as "any unexpected, unplanned, undesirable, or severe reaction to a drug that requires discontinuation of the drug, change in drug therapy, dose (other than minor dosage adjustments), hospitalization, length of hospital stay, supportive treatment, significantly complicated diagnosis, or harm to the patient." Additionally, this concept encompasses allergies and unusual reactions for medical professionals.

Research Methodology

The patients who took part in the trial gave their informed permission. The research was an observational pharmacovigilance questionnaire. Demographic information (age, sex, residence, etc.), medical history, current medication therapy, adverse drug reaction (ADR) description, evaluation, and treatment details were all gathered. Researchers at a large academic medical center's tertiary care pulmonary medicine (TB & chest) outpatient department conducted the testing. Using a systematic questionnaire, researchers questioned around 150 patients with established asthma, regardless of age or sex, during the course of the trial. The evaluation of unfavorable events' causation was done using Naranjo's probability scale. There was an option to indicate "yes," "no," "unknown," or "do not know" for each question. The overall score determined the likelihood group to which the ADR was assigned: certain > 9, likely 5-8, plausible 1-4, and questionable < 0. Levels 1 and 2 were considered mild, levels 3 and 4 were considered moderate, while levels 5, 6, and 7 were considered severe according to the Hartwig and Siegel scale, which was used to evaluate the severity of ADRs.

Material & Methods

One hundred fifty individuals who visited an outpatient asthma clinic at a major medical center were the subjects of this prospective observational research. Once the research was approved by the Institutional Ethical Committee, it could begin. At enrollment, all patients were asked to sign a written informed consent document in the local vernacular language. The research included patients who had been diagnosed with Bronchial Asthma. For a duration of three months, the patients were monitored on a weekly basis. Information on the patient's demographics, medications, and pertinent laboratory tests were gathered. The enrolled patients' prescriptions were collected and examined. Patient information on their medications included the following: drug or combination name, dose form, daily dosage, frequency, generic or brand name of the prescribed medicine, and any co-prescribed pharmaceuticals. Analyzing the temporal connection of drug usage with Adverse Drug Reactions demonstrated the causative link of adverse drug effects. The Modified Hartwig and Siegel scale was used for severity evaluation, whereas the WHO UMC causality assessment scale was used for causality evaluation.

Inclusion Criteria

- Age range: 18–70 years.
- Gender: men and women.
- People suffering from bronchial asthma.
- Individuals capable of providing informed permission

Exclusion Criteria

- Must be between the ages of 18 and 70.
- Women who are carrying a child or who are nursing a child.

- Individuals afflicted with asthma.
- People suffering from ailments affecting the whole body.
- Having taken part in a different clinical trial within the last three months.
- People using other medications.
- Those patients who refuse to provide their informed consent

Statistical Analysis: After data was input into an Excel spreadsheet, suitable tests were used for data analysis.

Results

Table 1 is a list of the medications that are most often prescribed to asthmatic patients. From the findings of the demographics study, it was determined that the sample population consisted of a greater number of females than men. A significant proportion of the participants were in the age range of forty to fifty years old. The findings of this research indicated that the majority of the participants were given multiple medication therapy as opposed to receiving treatment with a single drug regimen. Within the context of multiple drug treatment, the administration of two pharmaceutical therapies was more common than the administration of combinations of three or four medications. β2-agonists were the most often recommended medications for asthmatics, followed by methylxanthine and corticosteroids as the next most popular medications. Histamines, which are commonly delivered in the form of pills, inhalers, and other formulations such as syrup, are the anti-asthmatic drug that is recommended the least often.

Table 1: Treatment medications for asthma

Category	Name of drug
Corticosteroids	Beclomethasone, Budesonide
β agonist	Salbutamol, Terbutaline, Salmeterol
Methylxanthine	Theophylline, Etophylline
Leukotriene agonist	Montelukast
Anti-histamines	Loratadine
Anticholinergics	Benztropine, Trospium chloride

Table 2: Drug treatment plan (single or multiple medication plan)

Drug therapy	No of subjects	Percentage
Single drug	23	15.3
Multiple drug	127	84.6
Two drugs	86	67.7
Three drugs	24	18.8
Four drugs	17	13.3

Table 2: provides an analysis of the medication treatment regimens that were prescribed to the individuals who participated in the research. It emphasises the prevalence of multiple-drug therapies in the management of asthma. Out of the total of 150 participants, 127 (84.6%) were given a prescription for a multiple-drug regimen, while only 23 (15.3%) were treated with a single-drug treatment. The two-drug combinations were the most prevalent among the participants who were on the multiple-drug regimen, which meant that 86 of them (67.7%) were involved. Combining drugs that have mechanisms of action that are complimentary to one another is presumably the goal of this method, which is meant to promote improved symptom management. Eighteen percent of the individuals were administered three drug regimens, while thirteen-point three percent of the subjects were given four drug regimens. The four-drug regimens were frequently recommended to patients who had severe or uncontrolled asthma and required a more thorough treatment strategy. When it comes to properly controlling asthma, the results highlight the significance of personalised and combination medicines. The use of numerous medications is effective in treating a variety of pathophysiological elements of asthma; nevertheless, it also requires careful monitoring in order to reduce the likelihood of adverse drug responses and improve patient compliance.

Table 3: Medication dosage

Dosage form	Number of prescriptions	Percentage
Tablet	112	74.6
Inhaler	26	17.3
Syrup	12	8

Tablets were the most often prescribed form, accounting for 112 prescriptions or 74.6% of the total. This information is shown in Table 3, which analyses the distribution of dosage forms that are utilised in asthma prescriptions. As a result of their comfort and simplicity of administration, tablets are often the medication of choice for a significant number of patients. Inhalers, which were administered in 26 patients (17.3%), are a vital type of asthma therapy because they transport medicine directly to the airways, therefore giving quick symptom relief and decreasing the severity of systemic adverse effects. One possible explanation for the very low prescription rate of these inhalers is that patients may have trouble using them correctly, or that there are limited indications for their usage in mild instances. Syrups were the least used form, accounting for 12 prescriptions (8%), and were most likely reserved for paediatric patients or those who were unable to handle solid dose forms. The findings underscore the need of taking into account patient-specific factors when developing pharmacological formulations, with the goal of striking a balance between effectiveness, convenience, and adherence. For asthma therapy, increasing the use of inhalers in situations when they are suitable might enhance symptom control and lessen systemic effects, despite the fact that tablets are the most used prescribed medication.

Conclusion

This research highlights the intricate process of asthma management, where combination medications are often used to tackle the complicated nature of the condition. Finding a balance between effectiveness and safety in personalised treatment regimens is crucial, as shown by the outcomes. Combination therapy including β2-agonists and corticosteroids were given to most patients. This treatment improved symptom management but needed close monitoring for adverse drug reactions. The most often recommended dose type was still tablets because of how easy they were to use, but inhalers were necessary for more serious cases since they provided quick relief. To increase adherence and outcomes, the results suggest that patients should be better educated on how to utilise their medications, especially inhalers. The research also shows how important it is to have good pharmacovigilance procedures to keep an eye out for adverse drug reactions and make sure asthma is managed safely and effectively. Further optimisation of asthma treatment via the exploration of cost-effective, patient-centric solutions requires ongoing study.

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