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Research Paper

Assessment of Adverse Drug Reactions to Antibiotics: A Hospital Survey

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ABSTRACT

Pharmacovigilance has evolved significantly with advancements in data analytics, enhancing drug safety evaluation and the monitoring of adverse drug reactions (ADRs). Historically, ADR reporting was minimal, but legal requirements now mandate this practice in many regions. Pharmacovigilance plays a crucial role in medical interventions, focusing on patient safety by assessing the risk-benefit profile of medicines. The World Health Organization (WHO) defines it as activities related to detecting, assessing, and preventing adverse drug effects. The first formal pharmacovigilance organization was established in 1938 following fatalities due to sulfanilamide elixir. In 1968, WHO launched the Programme for International Drug Monitoring to centralize global ADR data. Continuous monitoring is essential to maximize drug benefits while minimizing risks. In India, pharmaceutical companies are investing in research and development, necessitating robust pharmacovigilance standards. Antibiotics, critical in treating bacterial infections, face challenges due to rising antimicrobial resistance (AMR), complicating treatment of common diseases. Misuse of antibiotics exacerbates this issue, making infections harder to treat. Antibiotics like amoxicillin, ciprofloxacin, and azithromycin are commonly used but associated with significant ADRs, especially in children. Understanding the causality and severity of these reactions is vital for safer pediatric use. This review emphasizes the importance of pharmacovigilance in mitigating risks associated with antibiotic therapy, ensuring drugs are used effectively while minimizing potential adverse effects. The integration of pharmacovigilance in drug development and clinical practice is crucial for optimizing patient safety and therapeutic outcomes.

INTRODUCTION

1.1. Pharmacovigilance.

Over the past few decades, the evaluation of drug safety and the balance between their benefits and harms has been significantly transformed by the availability of large databases and computerized

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automated statistical analyses. Although the reporting of adverse drug reactions (ADRs) is increasingly common and is now legally required in several countries, this has not always been the case [1]. A century-long history of many tragic events has played a critical role in shaping the present-day drug development structures and processes, none more so than those concerned with pharmacovigilance [2]. Pharmacovigilance is an important element of any medical intervention which aims at enhancing patient safety by assessing the risk-benefit profile of medicines [3]. It is defined by WHO as "The science and activities related to the detection, assessment, understanding and prevention of adverse drug effects toxicity or any other possible drug-related problems" [4]. The first governmental organization of pharmacovigilance was created in 1938 with the foundation of the Federal Food, Drug and Cosmetic Act, after more than 100 deaths had occurred in the United States of America because of the use of sulfanilamide elixir, containing diethyl glycol as the solvent [5]. In 1968, the World Health Organization (WHO) promoted the "Programme for International Drug Monitoring", a pilot project aimed to centralize world data on adverse drug reactions (ADRs). In particular, the main aim of the "WHO Programme" was to identify the earliest possible PV signals [6]. Continuous monitoring of drug effects, side effects, contraindications and outright harmful effects which could result in a high degree of morbidity, and in some cases, even mortality, are essential to maximize benefits and minimize risks [7]. The leading Indian companies, realizing the compulsions of the new regime, have already initiated investments of substantial resources for the discovery and development of new drugs needed for both Indian and International markets. This in turn means that during the coming year, research and development by the Indian pharmaceutical and biotech companies will hopefully lead to new drugs based on pre-clinical and clinical data generated mostly in India. With the Indian companies' capacity to develop and market new drugs out of their own research efforts, it is important that adequate PV standards are introduced to monitor ADRs of products first launched in India [8]. Drugs are the most common medical interventions, primarily used to relieve sufferings. But it has been recognized long ago that drug themselves can prove fatal; as the saying rightly goes ''Drugs are Double Edged Weapons''. Adverse reaction monitoring and reporting are very important in identifying the adverse reaction trends in local population [9]. In its simple definition an ADR is any undesirable effect of a drug beyond its anticipated therapeutics occurring during clinical use. The WHO defines an ADR as ''any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.'' Thus this definition excludes overdose (either accidental or intentional), drug abuse, and treatment failure and drug administration errors [10]. Adverse drug reactions (ADRs) are a public health problem, especially in pediatric populations. Children are more susceptible to such reactions compared to adults, due to their immature physiological processes and the lack of drug testing and indication in this age group [11]. These reactions result in unplanned hospital admissions, prescription of complementary pharmacotherapy, and economic losses to caregivers and health services [12]. Therapeutic agents, such as antibiotics, are associated with a high incidence of ADRs in children, resulting in unplanned hospital admissions and stay [13]. A recent study that examined serious ADRs in children, reported that antibiotics were most associated with disproportionate reports, serious ADRs, and suspected death [14]. Therefore, an improved

understanding of the causality, severity, and avoidability of antibiotic-associated ADRs is critical to safety in pediatric populations. These data facilitate the design of strategies to better manage adverse reactions [15].

1.2. Anti-Biotic drugs:

Antibiotics are medicines used to prevent and treat bacterial infections [16]. The introduction of antibiotics into clinical use was arguably the greatest medical breakthrough of the 20th century. Antibiotic resistance is rising to dangerously high levels in all parts of the world [17]. However, misuse of these valuable compounds has resulted in the rapid rise of antimicrobial resistance (AMR) with some infections now effectively untreatable [18]. New resistance mechanisms are emerging and spreading globally, threatening our ability to treat common infectious diseases. A growing list of infections such as pneumonia, tuberculosis, gonorrhea, and food borne diseases are becoming harder, and sometimes impossible, to treat as antibiotics become less effective [19]. Penicillin medication is used to treat several kinds of bacterial infections. It is also used for the treatment of a number of infections like pneumonia, bronchitis, gonorrhea and infections of the ears, nose, throat, urinary tract and skin [20]. The antibiotic should be prescribed only in case of bacterial infections, when the symptoms are severe, high risk of complications, and infection is not resolving [21]. Antimicrobial side effects present as adverse drug reactions involving one or more organ systems. Although most antibiotics are safe considering their volume of use, some antimicrobials have the potential for life-threatening side effects. In general, p-lactams have the least frequent and least severe side effects. Although any antibiotic is capable of causing side effects, specific agents from each antibiotic class are more likely to do so than others [22]. The mechanism of antibiotic-related anemia varies according to the antibiotic being used. For example, p-lactams may cause autoimmune hemolytic anemia. TMP-SMX may be associated with folate deficiency, which may result in a megaloblastic anemia [23]. Eosinophilia may be associated with any antibiotic causing a drug fever but may occur with fosfomycin in the absence of drug fever. Chloramphenicol rarely may cause irreversible aplastic anemia [24]. Antibiotics are life-saving drugs, should be used safely and effectively. Many antibiotics such as amoxicillin, ampicillin, cephalosporin, *etc*. cause mild side effects such as diarrhea and abdominal pain, and need to be prescribed with appropriate stomach care supplement or probiotics [25].

1.2.1. Commonly used antibiotics:

1. **Amoxicillin:** Amoxicillin is a broad-spectrum, beta-lactam antibiotic used to treat infections caused by gram-positive and gram-negative bacteria. It is commonly used for ear infections, strep throat, pneumonia, and urinary ract infections.
2. **Ciprofloxacin:** Ciprofloxacin is a fluoroquinolone antibiotic effective against a wide range of gram-negative and gram-positive bacteria. It is often used to treat urinary tract infections, respiratory infections, and skin infections.
3. **Azithromycin:** Azithromycin is a macrolide antibiotic used to treat respiratory infections, skin infections, and sexually transmitted infections. It works by inhibiting bacterial protein synthesis [26].

1.2.2. Therapeutic uses:

1. **Respiratory Tract Infections**: Antibiotics like amoxicillin are commonly prescribed for bacterial pneumonia and bronchitis to eliminate the pathogenic bacteria causing these conditions [27].

2. **Urinary Tract Infections**: Ciprofloxacin and trimethoprim-sulfamethoxazole are effective in treating urinary tract infections (UTIs) by targeting common uropathogens like E. coli.
3. **Orthopedic Surgeries**: For procedures involving implants, antibiotics like cefuroxime are used prophylactically to prevent infection, ensuring the successful integration of the implant [28].
4. **Prevention of Surgical Site Infections (SSI)**: Prophylactic antibiotics such as cefazolin are administered prior to surgery to prevent infections in surgical wounds by inhibiting the growth of potential pathogens [29].

METHOD:

The study was conducted from 2 may to 12 may at three hospitals which are as follows Shiv krupa Ambap, Shrike Hospital Vathar tarf Vadgaon and Shiv Krupa Clinic Islampur, 1634km away from the capital of India, New Delhi.

RESULT:

A total of 103 patients were included in the final analysis with a mean age of 52.17 years and a male majority (69%), ensuring a relatively mature demographic, likely experiencing a range of chronic and acute health conditions that necessitate antibiotic treatment. Amoxicillin was the most widely prescribed medication followed by ciprofloxacin and azithromycin.

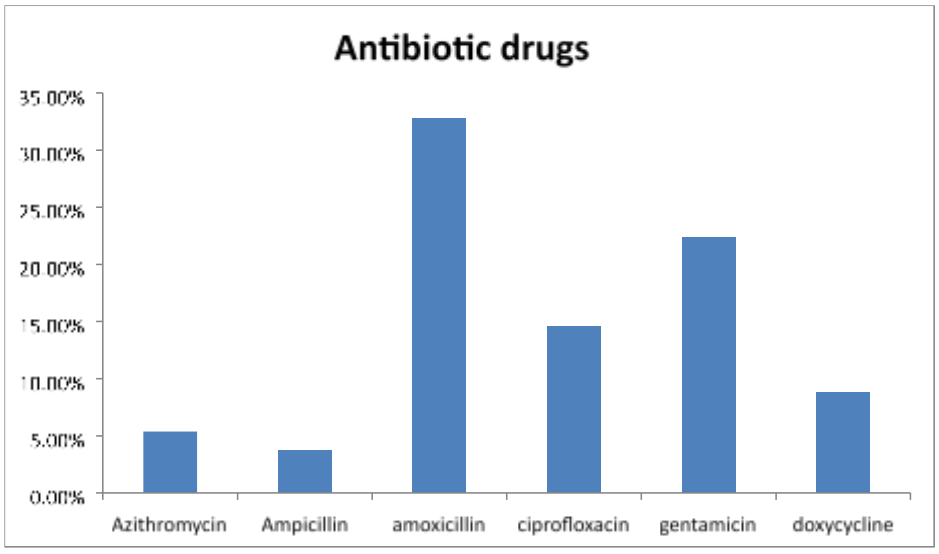

Figure No. 01. Antibiotics prescribed by doctors.

The study meticulously recorded the dosages and usage patterns of six prominent antibiotics: Azithromycin, Ampicillin, Amoxicillin, Ciprofloxacin, Gentamicin, and Doxycycline. Azithromycin was observed to have an average dosage of 5.37%, indicating its prevalent use for treating bacterial infections like respiratory infections. Ampicillin, with an average dosage of 3.68 %, is commonly employed to combat infections such as pneumonia, bronchitis, and urinary tract infections. Amoxicillin, notably higher in average dosage at 32.76%, is a widely used antibiotic effective against a broad spectrum of bacterial infections, ranging from ear infections to skin infections. Ciprofloxacin, administered at an average dosage of 14.57%, is particularly effective for more severe infections such as those affecting the bones and joints, intra-abdominal infections, and certain types of infectious diarrhea. Gentamicin, with an average dosage of 22.39%, is typically reserved for serious infections; especially those caused by Gram-negative bacteria, and are

often used in hospitals for infections that are resistant to other antibiotics. Doxycycline, at 8.81 units, is another versatile antibiotic, commonly used for treating conditions like acne, urinary tract infections, intestinal infections, respiratory infections, eye infections and periodontitis (gum disease). The data collected was systematically categorized and analyzed, providing valuable insights into the optimal usage patterns for these antibiotics. The choice of antibiotics and their respective dosages reflected current medical practices and guidelines, aiming to optimize therapeutic outcomes while minimizing potential resistance development and side effects. Azithromycin commonly caused gastrointestinal disturbances, including nausea, vomiting, diarrhea, and abdominal pain. Ampicillin and Amoxicillin, both penicillin derivatives, frequently resulted in allergic reactions, ranging from mild rashes to severe anaphylactic responses. They also caused gastrointestinal issues, including diarrhea and, less commonly, pseudomembranous colitis due to Clostridium difficile overgrowth. Ciprofloxacin, a fluoroquinolone, was associated with tendonitis and tendon rupture, particularly in older adults, as well as CNS effects like headaches, dizziness, and, in some cases, seizures. Gentamicin, an aminoglycoside, presented nephrotoxicity and ototoxicity risks, leading to kidney damage and hearing loss, respectively, especially with prolonged use or higher doses. Doxycycline, a tetracycline antibiotic, often resulted in photosensitivity, making patients more prone to sunburns, along with gastrointestinal discomfort such as esophagitis and gastritis. Each antibiotic's adverse effect profile necessitates careful consideration in clinical settings to balance therapeutic benefits with potential risks.

Table No. 1. Number of patients having adverse effects (in %)

Sr. No.	Adverse effect	No. of Patients (%)
1.	Nausea	32.7%
2.	Vomiting	26.95%
3.	Diarrhea	39.13%
4.	Abdominal pain	41.3%
5.	Skin rashes	19.36%
6.	Gastritis	13.47%
7.	Headache	29.13%

The adverse effects of a medication were meticulously documented in a clinical study, revealing varying frequencies among patients. Among the most commonly reported side effects, abdominal pain topped the list with 41.3% of patients experiencing discomfort, indicating a significant incidence within the study group. Diarrhea followed closely behind at 39.13%, highlighting another prevalent gastrointestinal issue associated with the medication. Nausea affected 32.7% of patients, while vomiting was reported by 26.95%, indicating substantial gastrointestinal disturbances overall. Beyond gastrointestinal symptoms, skin rashes were noted in 19.36% of cases, suggesting a notable but comparatively lower occurrence compared to gastrointestinal issues. Gastritis, another gastrointestinal concern, affected 13.47% of patients, further emphasizing the medication's impact on digestive health. Headaches were reported by 29.13% of individuals, marking a significant neurological symptom associated with the drug. These findings underscore the complexity and diversity of adverse reactions associated with the medication in question. The high prevalence of gastrointestinal symptoms such

as abdominal pain, diarrhea, nausea, and vomiting suggests a profound impact on digestive physiology for many patients. Concurrently, the occurrence of skin rashes and headaches highlights additional areas of concern that clinicians must monitor and manage during treatment. In clinical practice, understanding and mitigating these side effects are crucial to optimizing patient care and adherence to therapy. Clinicians must weigh the benefits of the medication against its potential adverse effects, employing strategies to minimize discomfort and maximize therapeutic efficacy for each individual patient.

Level of adherence:

Table No. 2. Level of Adherence.

Level of adherence	Number (percentage)
Good (> 80%)	63 (61.16%)
Poor (< 80%)	40 (38.83%)

The adherence levels to antibiotic drug regimens among 103 patients were evaluated, revealing insightful statistics. A majority of the patients, accounting for 61.1% (66 individuals), demonstrated good adherence (> 80%) to their prescribed antibiotic treatments. In contrast, 38.9% (42 individuals) exhibited poor adherence (< 80%), indicating a significant portion of the cohort struggled to comply with their prescribed regimens. These findings underscore the importance of monitoring and enhancing patient adherence to antibiotic therapies to ensure effective treatment outcomes and mitigate the risks associated with antibiotic resistance. Efforts to improve patient education and support mechanisms could potentially lead to better adherence rates and overall health outcomes among patients receiving antibiotic treatments.

Reasons for Poor Adherence:

Table No. 3. Level of Adherence.

Reasons for poor adherence	
Forgetfulness	26 (25.24%)
Economic reasons	4 (3.88%)
Drug cause discomfort or malaise	3 (2.91%)
BP was normal	1 (0.97%)
BP was low	2 (1.94%)
Unavailability of drugs in market	4 (3.88%)
Fasting	13 (12.62%)
Traveling	6 (5.82%)

The data on reasons for poor adherence among patients receiving antibiotic treatments offers valuable insights into the challenges individuals face in maintaining consistent medication routines. Forgetfulness emerges as the most prevalent factor contributing to poor adherence, affecting 25.24% (26 patients) of the cohort. This highlights a common issue where patients may simply overlook or forget to take their prescribed medications as directed, potentially compromising treatment efficacy. Economic reasons, cited by 3.88% (4 patients), also play a role, indicating

financial constraints that hinder patients from purchasing or refilling their prescribed antibiotics. Similarly, discomfort or malaise caused by the drugs themselves affects 2.91% (3 patients), leading to reluctance or inability to adhere to the treatment plan due to adverse side effects. Interestingly, blood pressure (BP) status appears as a contributing factor, albeit less frequently. A small percentage of patients (0.97% and 1.94% respectively) reported normal or low blood pressure as reasons for poor adherence, possibly due to misconceptions or concerns related to the interaction between antibiotics and BP levels. Furthermore, logistical challenges such as unavailability of drugs in the market (3.88%, 4 patients) and lifestyle factors like fasting (12.62%, 13 patients) and traveling (5.82%, 6 patients) also contribute significantly to non-adherence. These circumstances disrupt regular medication schedules, making it difficult for patients to consistently adhere to their antibiotic regimens. Understanding these reasons for poor adherence underscores the need for tailored interventions and patient education strategies. Addressing issues like forgetfulness through reminders, providing financial assistance or alternative medications for economic reasons, and offering support for managing drug-related discomfort are essential steps toward improving adherence rates and optimizing treatment outcomes in antibiotic therapy. Efforts to mitigate these barriers can enhance patient compliance, thereby reducing the risks associated with incomplete or irregular antibiotic use such as treatment failure and antibiotic resistance.

CONCLUSION:

The evaluation of antibiotic use and pharmacovigilance emphasizes the critical balance between therapeutic benefits and potential adverse drug reactions (ADRs). Historically, pharmacovigilance has evolved to improve drug safety, driven by numerous tragic events that underscored the need for stringent monitoring systems. The establishment of organizations like the WHO's Programme for International Drug Monitoring marked significant progress in identifying and mitigating ADRs. The importance of antibiotics, pivotal in treating bacterial infections, is contrasted by the rising challenge of antimicrobial resistance (AMR), exacerbated by misuse and overprescription. Commonly used antibiotics such as amoxicillin, ciprofloxacin, and azithromycin demonstrate varying efficacies against infections but also pose risks of adverse effects, particularly in vulnerable populations like children. The study conducted at three hospitals revealed prevalent use of antibiotics, with amoxicillin being the most prescribed, followed by ciprofloxacin and azithromycin. Adverse effects, including gastrointestinal disturbances and allergic reactions, were documented, highlighting the necessity for careful consideration in clinical practices. Patient adherence varied, with a significant portion displaying poor adherence due to factors like forgetfulness and economic constraints, impacting overall treatment outcomes. This data underscores the importance of pharmacovigilance in ensuring safe antibiotic use, enhancing patient safety, and curbing the development of resistance. It calls for comprehensive strategies, including patient education, adherence monitoring, and the prudent prescription of antibiotics, to optimize therapeutic benefits while minimizing risks. Such measures are crucial in safeguarding the efficacy of antibiotics and addressing the public health challenges posed by ADRs and AMR.

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