International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 3 May-June 2023, pp: 2697-2702www.ijprajournal.com ISSN: 2249-7781

Study on Adverse Drug Reaction in the Pulmonology Department of a Tertiary Care Hospital

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Submitted: 09-06-2023 Accepted: 19-06-2023

ABSTRACT: Background: ADRs (adverse drug reactions) are becoming a vital aspect of patient care and assessment. ADRs account for about 2% of all hospitalizations, according to the incidence rate. Medications with a narrow therapeutic index need ADR control rather than others. ADR research is required to determine the prevalence of ADRs in medical inpatients, estimate the impact of ADRs to hospital admissions, classify the types of ADRs found, identify possibly contributing risk factors, as well as estimate the costs of ADRs in terms of ADR-related excess stay in the hospital.

Objective: The main objective of the study was to study adverse drug reactions in pulmonary medicine department of a Tertiary care hospital, Hyderabad, Telangana, India.

Methodology: For a Five-month period, a prospective, descriptive, cross-sectional study was conducted in the pulmonary medicine department of a Tertiary care hospital in Hyderabad,Telangana,India. ADRs that occurred in the ward were closely tracked, and the collected reports were analysed for demographic profile, type of ADRs, ADR occurrence and drug causing ADR, severity assessment, and ADR management.

Results: During the study period, 80 patients' records were obtained from the pulmonary medicine department of a Tertiary care hospital. ADRs were registered in 17 of the patients. The demographics of ADR patients were analysed, and it was discovered that the prevalence of ADR was highest in the age group of 40-55 years (5 out of 17) and lowest in the age group of <=39 years. The therapeutic drug groups most often involved in ADRs were investigated. The most common culprits among the medications are first-line TB drugs, which account for 4 (23%) ADRs, corticosteroids, which account for 5 (29%) ADRs and other drugs used for different indications, such as ipratropium, Salbutamol, furosemide, Montelukast,Anti-bacterial and so on, which account for 8 (47%) ADRs. Hepatotoxicity, headache, Constipation, and Cough were the most widely recorded ADRS in this study.

Conclusion: ADRs are more prevalent in the elderly, and Corticosteroids drugs are more often implicated. The majority of the reactions were moderate. As a result, early identification, assessment, and control of ADRs are critical for reducing patient harm and improving public health.

KEYWORDS: Adverse drug reactions, Pulmonology, Tertiary care hospital, Pharmacovigilance, Patient safety

I. INTRODUCTION

Adverse drug reactions (ADRs) and other drug-related conditions lead to serious health and quality-of-life concerns. According to research conducted in various settings, adverse drug reactions account for 5 to 35 percent of hospitalizations. (ADR) The World Health Organization (WHO) describes an adverse drug reaction (ADR) as any noxious, unexpected, or unwanted consequence of a drug which appears in humans at doses used for prophylaxis, diagnosis, or therapy. Among hospitalized patients, ADRs are the fourth to sixth leading cause of death (Gallelli, Ferren et al., 2003; Galli, Pandya et al., 2017; Petrova, Steimenova et al. 2017, Maqbool, Ikrum et al., 2018) Adverse related incidents (ADRs) account for 1.9-5.6 percent of all admissions, with ADRs affecting about 35 percent of hospitalized patients. ADRs not only raise mortality and morbidity, but they also increase the cost of health care. Drugs with a narrow therapeutic index need ADR control rather than others. For several years, theophylline has been used to treat asthma and COPD (Gallelli, Ferreri et al. 2003; Petrova, Stoimenova et al., 2017; Hanlon, Nicholl et al. 2011; Maqbool, Shabbir et al. 2018) Theophylline-related ADRs were found to be 4.71 percent of the time, with nausea, anorexia (loss of

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 3 May-June 2023, pp: 2697-2702www.ijprajournal.com ISSN: 2249-7781

appetite), and palpitation being the most common symptoms ADRs must be studied in order to assess the prevalence of ADR in medical inpatients, estimate the contribution of ADRs to hospital admissions, classify the types of ADRs found, identify possibly contributing risk factors, as well as estimate the costs of ADRs in terms of ADR-related excess stay in the hospital (Hire, Kale et al. 2014; Singh. Prasad et al. 2015; Parova, Stoimenova et al., 2017, Maqbool, Dar et al. 2019). Adverse drug reactions (ADRs) associated with medications used to treat pulmonary disorders pose a significant health risk to patients, ADR that are serious or potentially lethal are often detected with commonly used medications Premarketing clinical trials are used to determine the advantages and adverse effects of new products before they are approved for sale. However, the scale) of these trials is usually limited to 120 patients, making it difficult to identify unusual ADRs prior to approval. When previously unknown but serious ADRs are identified after a medication has been approved by the US Food and Drug Administration (FDA), information is disseminated through updated product inserts (PIS), so-called Dear Doctor letter and/or journal publications Despite the fact that medical professionals and patients rely on this information to ensure safe medication use, ADR documentation is often delayed and formatted inconsistently (Brettner, Robert Heitzman et al. 1970: Scesai, Cappellato et al., 2001; Bhunanker. O'Donnell et al. 2005: Banisadi and Fahimi 2011; Fens, Zhou et al, 2021). This study was performed in the pulmonary medicine department of a Tertiary care hospital in Owaisi hospital and research centre, Hyderabad, Telangana, India, to investigate adverse drug reactions.

II. METHODOLOGY

This 4-month research took place in the Pulmonary Medicine department of a Owaisi hospital, Hyderabad,Telangana,India. The treatment chart of patients in the ward of the pulmonary medicine department was included in this prospective descriptive, cross-sectional analysis. Hospital approval was obtained from the medical superintendent before initiating the study. Inclusion and exclusion criteria were used to recruit patients. Patients with an adverse reaction to medications used for a variety of indications, patients of both genders, and patients of all ages were included in the study, while prescriptions with insufficient patient information were omitted. The data was analysed using descriptive statistics.

The patient selection was random and the patient population was divided into four broad categories based on diagnosis as:

- Chronic obstructive pulmonary disease
- Infections (pneumonia, tuberculosis (TB), lower respiratory tract infection).
- Asthma
- Others (pleural effusion, anti-tubercular drug induced hepatitis, obstructive sleep apnoea, interstitial lung disease, pleurisy, obesity hypoventilation syndrome, corpulmonale)patients were monitored from the day of admission till the day of discharge. Sources of data were case sheets and verbal information while counselling the patients. The details were collected in patient profile form designed for the study purpose. The details included: Demographics, medical history, medication history, laboratory data, history of drug allergy along with causative drug, current therapy, suspected ADR, description of ADR, date of onset, management and outcome aspects. Suspected ADRs were reported, analysed and a causality assessment was carried out using Naranjo's algorithm scale.

III. RESULT

During the study period, 80 patients' records were screened from the pulmonary medicine department of a Tertiary care hospital. ADRs were reported in 17 of the patients.

Age Group	Total no. of Patients with ADRs	No. of Males	No. of females	%Distribution
<19	4	2	2	5%
20-29	3	1	2	3.75%
30-39	2	1	2	3.82%
40-55	5	1	4	6.37%
56-70	2	1	1	3.75%
Total	17	6	11	21.25%

TABLE 1.1 TOTAL NUMBER OF PATIENTS INCLUDED IN THE STUDY WITH RESPECTIVE TO AGE AND GENDER.

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INCIDENCE OF ADRS:
Out of the 80 patients treated for various indications, 17 (21.25%) patients were reported with an incidence of ADRs. Out of them 06 were male and 11 were female patients.

S.No	Type of ADR	No.of Pts	No.of Males	No.of female	%Distribution
1	Hepatotoxicity	2	0	2	11.76%
2	Headache	2	1	1	11.76%
3	Dysphagia	1	0	1	5.88%
4	Abdominal pain	4	2	2	23.52%
5	Constipation	2	0	2	11.76%
6	Oral thrash	2	1	1	12%
7	Dyspnoea	2	1	1	11.76%
8	Tremor	1	0	1	5.88%
9	Cough	1	1	0	12%
	Total	17	6	11	100

TABLE 1.2 LIST OF ADRS REPORTED DURING STUDY PERIOD

INCIDENCE OF ADRS:
a) Based on gender of patients:
A total of 17 patients with ADRs were detected out of which 06 were males and 11 were females.

Gender	No.of patients with ADR	No.of Patients without ADRs	Total	Incidence Rate
Male	06	26	32	18.75
Female	11	37	48	22.9
Total	17	63	80	21.25

TABLE 1.3 INCIDENCE OF ADRS IN THE PATIENTS WITH RESPECT TO GENDER

b) Based on the age of the patients:
Table shows the incidence of ADRs with respect to age

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Age (Yrs.)	No.of ADRs Patients	Total no.of Patients	Incidence Rate
<19	4	23	0.17
20-29	3	17	0.17
30-39	2	14	0.14
40-55	5	16	0.31
56-70	2	10	0.2

TABLE 1.4. INCIDENCE OF ADRS IN THE PATIENTS WITH RESPECT TO AGE

DRUGS CAUSING ADVERSE DRUG REACTIONS:

The most commonly occurring ADRs are due to the first lineAnti-TB drugs,ipratropium, corticosteroids, tramadol, Montelukast, salbutamol, and some Anti-bacterial agents.

Suspected Drug	No. of ADR	Percentage of ADRs
First line TB Drugs	4	23
Corticosteroids	5	29
Antimicrobials	3	17
others	5	29

TABLE 1.5. DRUGS MOST FREQUENTLY IMPLICATED FOR ADRS

Management of the Adverse Drug Reactions (ADRs): The management of the ADRs was done by taking following measures. The details are shown in the following

Measures	No. of patients
Drug withdrawn	3
No change	9
No change other Drugs added	5

TABLE 1.6. MANAGEMENT OF ADVERSE DRUG REACTIONS (ADRS)

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Outcome	No. of Patients	% of Outcome
Definite /highly probable	8	47
Possible	5	29
Probable	4	24
Unlikely	0	0

TABLE 1.7. CAUSALITY ASSESSMENT

IV. DISCUSSION

The physicians prompted spontaneous reporting method was used in this research. Adverse drug reaction reports were obtained from 17 patients (21.25 percent) of the 80 patients treated for different indications during the 5-month study period. The Naranjo scale revealed that out of 17 ADRs, 8 (47%) was listed as "Definite", followed by 5 (29%) Likely, and 4 (23%) "Probable" adverse drug reactions (Table 1.7). Hepatotoxicity, Headache, Cough, and Constipation were the most widely recorded ADRs in this study (Table 1.2). When the severity of ADRs was measured using Hartwig's severity scale, it was clear that the majority of the ADRs were mild (11 patients) to moderate (4 patients), with one serious (2 patients) reaction (Table 1.8). ADRs were often controlled by withdrawing the causative drug depending on the severity of the reaction. In the current research, 03 patients with drug-induced reaction were treated by switching medications, 09 patients were treated by adding other drugs to reduce the severity of ADRs, and 05 patients' prescriptions were not changed. There were no ADRs that caused permanent damage or resulted in the patient's death. The demographics of ADR patients were analysed, and it was discovered that the prevalence of ADR was highest in the age group of 40-55 years (5 out of 17) and lowest in the age group of 30-39 years (Table 1.4). The higher prevalence of ADRs in our study's extreme age groups (40-55 years) may be attributed to other co-morbidities or age-related disorders such as metabolic changes. The lower number of ADRs identified among those aged 30-39 years could be due to a lower prevalence and occurrence of pulmonary disorders in this age group, as well as a lower number of patients attending the hospital. ADRs were found to be more common in Females (11 patients) than males in this sample (06 patients).

This may be due to the fact that there are more Female patients in the ward than male patients. The therapeutic drug groups most often involved in ADRS were investigated. The most common culprits among the medications were found to be first-line TB drugs, which account for 04 (23%) ADRs, corticosteroids, which account for 5 (29%) ADRs, and other drugs used for different indications, such as ipratropium, salbutamol, furosemide, montelukast, Anti-bacterial and so on, which account for 8 (47%) ADRS (Table 1.5). This study's findings were close to those of several other studies that found these to be the most offending substances in their studies. ADR research is also necessary to assess their prevalence in medical practice, estimate their contribution to hospital admissions, classify the types of ADRS seen, identify predisposing risk factors, and estimate the costs of ADRs in terms of ADR-related excess hospital stays.

One pathway for more actively monitoring Adverse Drug Reactions (ADRs) and, as a result, improving patient care safety is a structured Adverse Drug Reaction Surveillance network. Multiple methods for testing and recording the efficacy of drugs in clinical use are important for avoiding or reducing patient injury and strengthening public health. This entails establishing a well-structured Pharmacovigilance programme in clinical practice. Once a prescription has been published into the "true world," pharmacovigilance is an important method of monitoring medication-related issues. Pharmacovigilance and other drug-related problems should be familiar to those whose life is impacted by prescription procedures in some way. In recent years, pharmacovigilance has gained prominence as a technology critical to sound clinical practice and public health science. Since ADRS have such a detrimental influence on patients' wellbeing and inflict too much financial strain, it's critical to carefully monitor each medication for any potential adverse effects in animal models (preclinical studies) and clinical trials until releasing it. Pharmacovigilance aims to

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play a key role in combating the dangers faced by an ever-growing number of drugs, each of which is vulnerable to unpredictably negative side effects. When adverse effects and toxicity occur, they must be recorded, analysed, and the importance of the results correctly communicated to those who may understand the evidence. By ensuring that prescription drugs of high consistency, purity, and effectiveness are used rationally, the risk of injury will be minimised (Salem, Manouchehri et al., 2018; Johnson, Manouchehri et al., 2019)

V. CONCLUSION

ADRs increase morbidity and mortality while also rising. healthcare costs. ADRs must be identified, measured, and tracked early in order to minimise patient damage and thereby improve public health. As a consequence, pharmacovigilance is an important post-market method for ensuring the safety and effectiveness of pharmaceuticals and other health-related products. Many research have been conducted separately on various respiratory diseases such as Hypoxemic Respiratory failure, tuberculosis, Pleural Effusion, Community Acquired Pneumonia, respiratory tract infections (upper/lower), and so on. However, this study included some of the most common diseases in this field, such as Asthma, tuberculosis, and respiratory tract. infections. A routine patient follow-up is needed for the early detection and prevention of ADRs in order to improve patient adherence to drug therapy and provide improved drug therapy by avoiding associated morbidity and mortality. Pharmacovigilance aims to play a critical role in addressing the risks faced by the ever-growing list of drugs, each of which carries the unavoidable risk of unpredictably harmful side effects. When adverse effects and toxicity occur, particularly when they are previously unknown, they must be registered, evaluated, and their importance effectively communicated to those with the ability to interpret the data. By ensuring that pharmaceutical products of good quality, protection, and effectiveness are used rationally, the risk of harm can be minimised.

ACKNOWLEDGEMENT

We express our thanks to Dr. S.A Azeez Basha, Principal, Deccan School of Pharmacy for necessary facilities, helping and motivating us during the project work. We also thank Mr. Syed Aamir Ali (Associate Professor, Department of Pharmacy Practice) for providing valuable guidance and continuous encouragement.

REFERENCES

[1]. Shamna M, Dilip C, Ajmal M, Linu Mohan P, Shinu C, Jafer CP, et al. A prospective study on Adverse Drug Reactions of antibiotics in a tertiary care hospital. Saudi Pharm J 2014; 22:303-8.
[2]. Nebeker JR, Barach P, Samore MH. Clarifying adverse drug events: A clinician's guide to terminology, documentation, and reporting. Ann Intern Med 2004; 140:795-801
[3]. World Health Organization. Handbook of Resolutions and Decisions of the World Health. Assembly and Executive Board WHA 16.36 Clinical and Pharmacological Evaluation of Drugs. Vol. 11948-1972. Geneva: World Health Organization; 1973.
[4]. Gholami K, Kamali E. Hajiabdolbaghi M. Shalviri G. Evaluation of anti-tuberculosis induced adverse reactions in hospitalized patients. Pharm Pract (Granada) 2006; 4:134-8.
[5]. Baniasadi S and F Fahimi. Adverse drug reactions in a pulmonary teaching hospital: Incidence, pattern, seriousness, and preventability, Current drug safety, 2011;6(4): 230-236.
[6]. Gallelli L, et al. Retrospective analysis of adverse drug reactions to bronchodilators observed in two pulmonary divisions of Catanzaro, Italy, Pharmacological research, 2003; 47(6): 493-499.
[7]. Hartwig SC, et al. Preventability and severity assessment in reporting adverse drug reactions, American journal of hospital pharmacy, 1992;49(9): 2229-2232.
[8]. Hanlon P, et al. Examining patterns of multimorbidity, polypharmacy and risk of adverse drug reactions in chronic obstructive pulmonary disease: a cross-sectional UK Biobank study, BMJ open, 2018; 8(1): c018404.