

# A Prospective Pharmacovigilance Study in the Respiratory Tract Infections in Pulmonary Medicine Department of a Tertiary Care Hospital

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## ABSTRACT

**Background:** Adverse drug reactions (ADR) are the known dangers of any medicinal therapy. They are not only responsible for increasing the mortality and morbidity but also for multiplying the health care expenditure. The **aim** of this study was Identify the utilization pattern of different drugs, monitoring, reporting and management of ADRs in Pulmonary Medicine Department of a Tertiary Care Hospital **Methods:** The study was prospective observational study which was carried out for a period of Three Month (April – June 2025) study in Tertiary Care Hospital. Patients included in the Pulmonary Medicine Department in respiratory disease Proportion of ADRs and patient characteristics were investigated. Causality was evaluated by the Naranjo algorithm, severity was determined using the Hartwig classification and preventability was assessed using the Schumock and Thornton scale. **Results:** One hundred and Five numbers (105) of ADRs were seen out of 150 patients of the study population. The occurrence of ADR was found slightly higher in males i.e., 55% as compared to females i.e., 45%. Most of the patients are affected with tuberculosis about 42 patients, asthma are 31 patients and acute pulmonary edema 19 patients. Causality assessment of ADR is identified According to naranjo scale. ADR were classified as is (0%) doubtful, (28%) probable (54%) possible and (18%) definite. ADRs observed yellow eyes (17%), nausea & allergy (15%), Palpitation which occurred in 14 cases i.e., 20.29%. Among 28 ADRs i.e., 43% belonged to the mild category, 46% moderate category and Severe 11% was found in the study. **Conclusion:** 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.

**Keywords:** Naranjo algorithm, Hartwig scale, Lower respiratory tract diseases.

## I. INTRODUCTION

India is a developing country with fourth largest producer of pharmaceuticals in the world with more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. It is also emerging as a clinical trial hub exposing larger population to newer drug treatments. Thus it is need of the hour to identify ADRs as early as possible and to prevent them, ensure the well being of the patient at reasonable cost<sup>[1]</sup>.

Lower respiratory tract infections (LRTI's) are among the most predominant causes of severe morbidity and mortality arising from infectious diseases both in developed and developing nations. A recent WHO report indicates that LRTI's account for 20% of the mortality among various infectious agents in Indian population<sup>[2]</sup>. Elaborating on possible predisposing factors will be critical to health care workers in the better management of patients suffering with Lower Respiratory Tract Infections (LRTI's). Children born to anaemic/malnutrition mothers, pre-term babies, low-birth weight, genetic disorders, birth anomalies and overcrowding are more predisposed to LRTI's<sup>[3]</sup>.

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<sup>[4]</sup>.

The aim of this study is to identify the utilization pattern of different drugs, monitoring, reporting and management of ADRs in pulmonology department.

The objectives of the present study was to examine the prevalence of adverse drug reactions for drugs used in treatment of respiratory tract infections and reporting of incidence that helps to improve the clinical condition of patients and reduce cost of treatments<sup>[5]</sup>.

## II. METHODOLOGY

**Study type:** A prospective Observational study.

**Study duration:** Three Months was conducted (From April -June 2025)

**Sample size:** 150 patients with Pulmonology Department

**Study site:** Suham (Asthma specialty hospital) and Bhavani Medical Center which is a 150 bedded hospital at Bhavani. Approximately about 75 patients are admitted in pulmonology department in per day. Equipped with advanced technology, the unit provides. Comprehensive services for pulmonology, diagnostics to complex treatments

### STUDY CRITERIA:

#### Inclusion Criteria:

- Infections (pneumonia, tuberculosis (TB), lower respiratory tract infection)
- Asthma and COPD
- Others (pleural effusion, anti-tubercular drug induced hepatitis, obstructive sleep apnea, interstitial lung disease, pleurisy, obesity hypoventilation syndrome, corpulmonale).
- Both male and female.

#### Exclusion Criteria:

- Infective and inflammatory diseases,
- Neoplastic patients,
- Psychiatric ill-patients,
- Pediatrics and Pregnant patients.

### STUDY PROCEDURE

Verbal Informed consent was sought from the patients before their enrollment, on the basis of inclusion and exclusion criteria. During the study, patients were monitored from the day of admission till the day of discharge. Sources of data were prescriptions, case sheets and existing records and documents. 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, management and outcome aspects. Suspected ADRs were analysed, reported and a causality assessment was carried out using Naranjo's algorithm scale. The severity assessment was carried out by using Hartwig's severity scale.

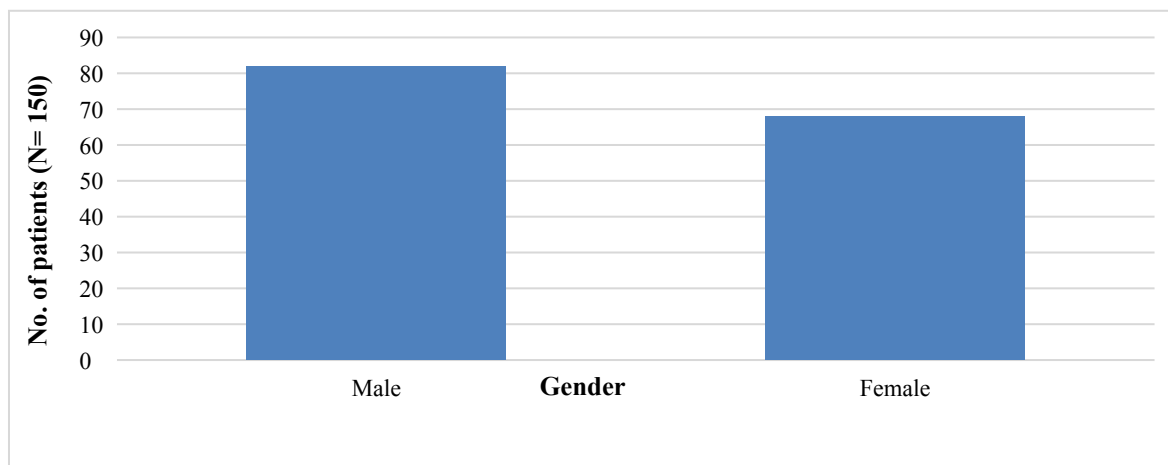
### STATISTICAL ANALYSIS

The data obtained was entered in the MS Excel. Descriptive Statistics can be used to describe the data. Categorical variables and percentages were used for the research.

## III. OBSERVATION AND RESULTS

### Gender-wise distribution:

A total of 150 patients were enrolled in the study. Out of this 82 (55%) were male and 68(45%) were female. (Figure 1)



**Figure 1: Gender-wise distribution in the study population,**

#### Types of diseases

Among 150 patients most of the patients are affected with tuberculosis disease about 42 patients, occupying 28%.

**Table 1: Disease wise incidence of ADR in the study population**

| Name of the Diseases  | Male<br>(N= 82) | Female<br>(N= 68) | Percentage<br>(%) |
|-----------------------|-----------------|-------------------|-------------------|
| Tuberculosis          | 26              | 16                | 28                |
| COPD                  | 14              | 10                | 16                |
| Asthma                | 16              | 15                | 21                |
| Pneumonia             | 11              | 12                | 15                |
| Acute Pulmonary Edema | 10              | 9                 | 12                |
| Lower RTI             | 5               | 6                 | 8                 |

The total no.of patients affected bythe asthma are 31 patients, occupying about 21%. The no.of patients affected by the acute pulmonary edema disease are 19 patients occupying 12%.

#### Mostly affected ADRs

From the above ADRs most of the patients are affected with Head ache and Yellow eyes, which contributes about 17%. In these males patients are affected more than the female patients. The Third most affected ADR is cough, breathing difficulty, which contributes about 14%. It is the common ADR in most of the diseases.

**Table 2: Distribution of Mostly affected ADRs**

| Types of ADR | No. of Patients | Male | Female | Percentage |
|--------------|-----------------|------|--------|------------|
|--------------|-----------------|------|--------|------------|

|                        | Mostly affected |    |    | (%) |
|------------------------|-----------------|----|----|-----|
| Nausea                 | 16              | 10 | 6  | 15  |
| Allergy                | 16              | 6  | 10 | 15  |
| Head Ache              | 18              | 10 | 8  | 17  |
| Breathing Difficulties | 15              | 9  | 6  | 14  |
| Cough                  | 15              | 8  | 7  | 14  |
| Yellow Eyes            | 18              | 12 | 6  | 17  |
| Sleepiness             | 15              | 7  | 8  | 14  |

#### Moderately affected ADRs

From the above data most of the female patients show common ADR with drowsiness which contributes about 13% of total number of patients affected with the ADR.

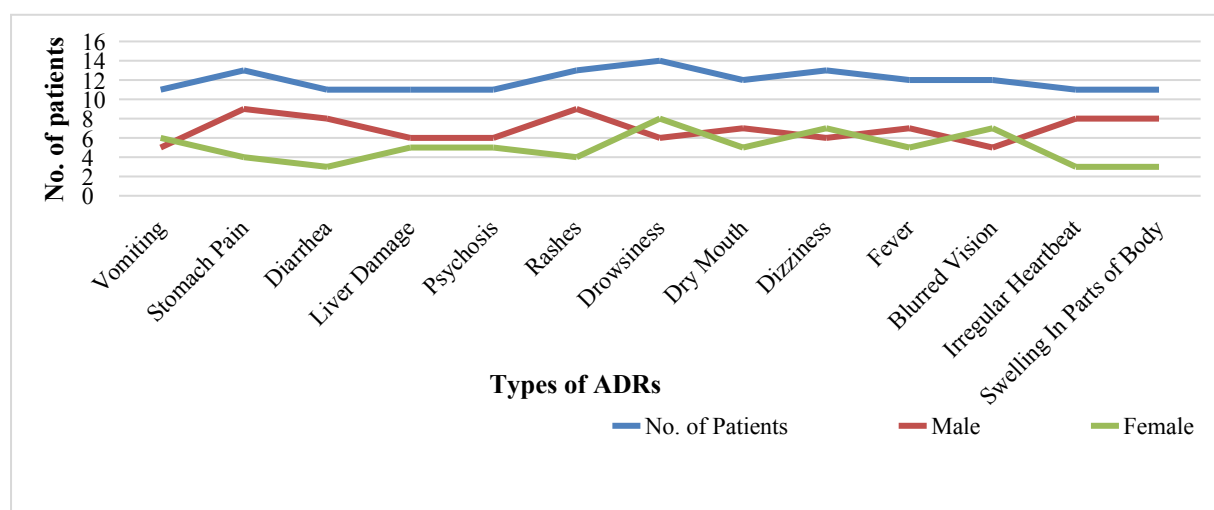


Figure 2: Moderately affected ADRs

#### Least Affected ADRs

The data mentioned above is the patients affected with least ADRs. It shows about 8 – 9% of the total ADRs affected.

Table 3: Distribution of Least Affected ADRs

| Types of ADR       | No. of Patients | Male | Female | Percentage (%) |
|--------------------|-----------------|------|--------|----------------|
| Depression         | 9               | 3    | 6      | 8              |
| Frequent Urination | 9               | 5    | 4      | 8              |
| Thirsty            | 10              | 5    | 5      | 9              |
| Nervousness        | 10              | 4    | 6      | 9              |
| Loss Of Appetite   | 10              | 7    | 3      | 9              |
| Palpitation        | 9               | 5    | 4      | 8              |
| Constipation       | 10              | 5    | 5      | 9              |
| Chest Pain         | 10              | 7    | 3      | 9              |

Depression and palpitation are least ADRs affected among all the patients which occupying about 8% of the patients. Nausea, vomiting, constipation are second least affected (NR=15) among all.

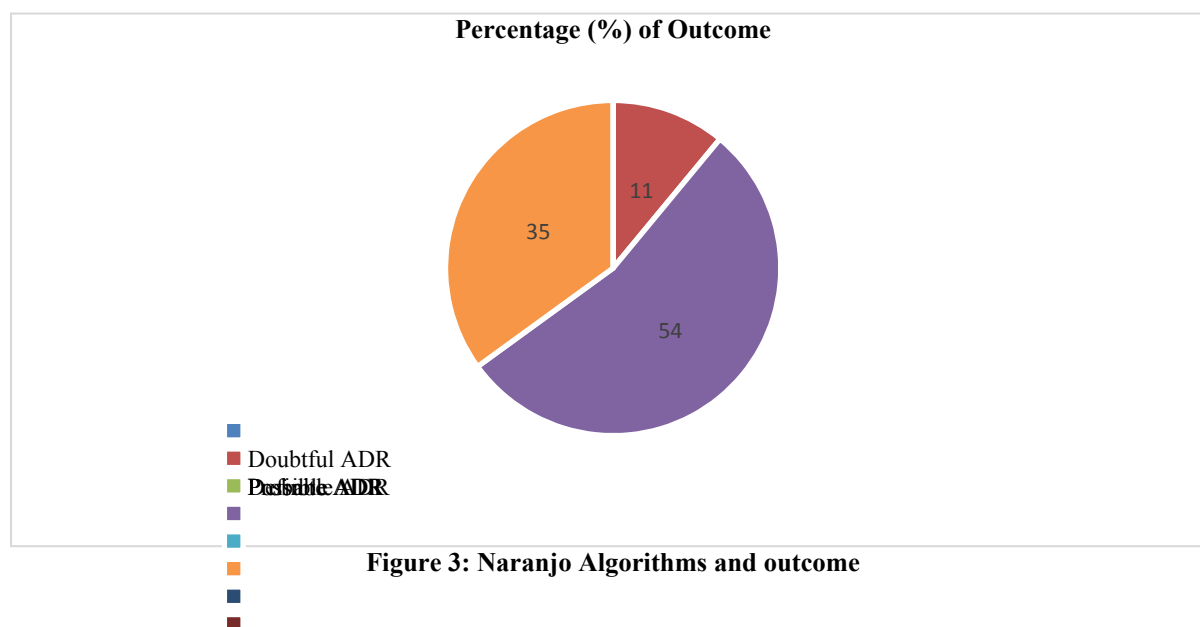
| Category of Drug  | No. of patients (NR=150) | Male (N=82) | Female (N=68) | Percentage (%) |
|-------------------|--------------------------|-------------|---------------|----------------|
| Antibiotics       | 83                       | 47          | 36            | 55             |
| Anti-Allergy      | 30                       | 15          | 15            | 20             |
| Bronchodilators   | 101                      | 57          | 44            | 67             |
| Anti Inflammatory | 45                       | 27          | 18            | 30             |
| Anti-Ulcer        | 39                       | 24          | 15            | 26             |
| Anti Tubercular   | 39                       | 24          | 15            | 26             |

**Table 4: Drugs prescribed in Respiratory patient**

Among all the above drugs bronchodilators are the mostly prescribed to the patients which contributes about 67% of the total number of drugs prescribed. The antibiotic contributes about 55% of the total no. of drugs prescribed. Antibiotics and Bronchodilators are the common drugs which are prescribed to most of patients with respiratory diseases.

#### Naranjo Algorithms and outcome

Among all the patients monitored, the causality assessment of ADR is identified in numbers and percentage according to Naranjo algorithm,



The majority ADR were classified as is 11% doubtful, 54% probable, 35% possible and 0% definite.

#### IV. DISCUSSION

Our study determines the incidence of ADRs in Pulmonology department and establishes the strategies to reduce and prevent the occurrence of ADRs. Such approaches will not only improve the quality of life of patients, but also minimize the cost associated with ADRs' contingency. This study was carried out in a tertiary care hospital (Bhavani medical Centre and Suham hospital) in accordance to the designed protocol.

In our study, we enrolled 150 patients of diagnosed by Pulmonologist of our tertiary care Hospital. This study was conducted after taking approval from the institutional ethics committee. In our study mainly the patients of COPD, Asthma, Bronchiectasis and ILD were enrolled after fulfilling the selection criteria.

The main aim of the study was to monitor different ADRs in this population of patients who are treated by different classes of drugs. At the same, we tried to find out the burden of ADRs in these patients, the association of ADRs with different drugs and overall picture of drug-ADR profile.

##### Demographic profile of the study population

In our study, gender distribution reveals that 55 % males and 45 % females were enrolled in our study which was in contrast to studies conducted by Oltmanns et al<sup>[8]</sup> where they enrolled 63 patients in which 47 males (75%) and 16 females (25%) were present. Tyagi et al carried out a study where 60 patients were enrolled in which 56 males (93.33%) and 4 females (6.67%) were present.

The data collection was done for a period of 3 months. The study was conducted in 150 patient's data in pulmonologist department. From that collected data, Male are 82 patients occupying about 55% of overall cases, where as female are 68 occupying about 45%. Most of the patients are affected with tuberculosis disease about 42 patients, occupying 28%. The second highest disease is asthma are about 31 patients, occupying about 21%.

##### Disease wise incidence of ADR

Disease wise incidence of ADR in the study population the patients who were on treatment for tuberculosis disease about 42 patients, Occupying 28%.showed highest percentage of

ADRs i.e., Asthma are 31 patients, occupying about 21%. Lower RTI (8 %) and lastly

##### Distribution of Mostly affected ADRs

Mostly affected ADRs Headache, cough is the ADR which is affected in most of the patients are 18 patients occurring about 17% Mohammed Zabeer et.al also supported the same finding that the majority of the ADRs are Headache and cough<sup>6</sup>.Drowsiness is the ADR that is occurred moderately which contributes about 13% of total number of patients affected with the ADR. Depression and palpitation are least ADRs affected among all the patients which occupying about 8%.

##### Drugs Prescribed in number of patients of RTI

Our study highlight several critical aspects of drug utilization and prescription patterns in the management of RTIs at a tertiary care hospital. The study observed a high prevalence of antibiotic use, with every patient in the study receiving at least one antibiotic. Most of the drugs prescribed among the patients are Bronchodilators male 57 patients, female is about 44 patients. On evaluation of the causality of ADRs, a majority of the reactions were probable (54%), followed by possible (35%) and doubtful (11%). There were no definite reactions Gholami,et.,al also supported the same findings that the probable reaction was the more<sup>7</sup>.

##### Causality assessment of adverse drug reactions

Naranjo algorithm was used to assess the causality which revealed that ADRs can be categorized into 54% probable, 35% as possible of ADRs as definite. These studies collect data on patient demographics, medication history, and observed ADRs, often using causality assessment tools like the Naranjo's scale to determine the likelihood of a drug causing an ADR. Key findings from such studies include the most frequent ADRs the most problematic drugs, and contributing patient factors, which helps improve patient safety and guide future treatment.

#### V. CONCLUSION

Pharmacovigilance studies on respiratory tract infections (RTIs) highlight the importance of potential adverse drug reactions (ADRs) specifically; these studies emphasize the need to address respiratory diseases such as COPD, tuberculosis, asthma, respiratory tract infections (upper/lower) ensure appropriate management of RTIs in vulnerable populations like the elderly.

Furthermore, they underscore the significance of monitoring ADRs and developing effective strategies for reducing the impact of RTIs on public health.

#### LIMITATIONS OF THE STUDY

The main limitation of this study is that it represents only the ADRs reported to the Department of pulmonary medicine and not the complete picture of ADRs occurring in the tertiary care center. The duration of hospital stay of the study patients due to ADRs and the related costs of ADRs were not calculated as there was no follow-up of the patients. The food-DI history was not elicited and analyzed.

induced adverse reactions in hospitalized patients. *Pharmacy Practice*. (Granada) 2006;4:134-8.

- [8]. Oltmanns U, Kahn N, Palmowski K, Träger A, Wenz H, Heussel C et al. Pirfenidone in Idiopathic Pulmonary Fibrosis: Real-Life Experience from a German Tertiary Referral Center for Interstitial Lung Diseases. *Respiration*. 2014;88(3):199-207

#### REFERENCES

- [1]. Sharma PK, Misra AK, Gupta N, Khera D, Gupta A, Khera P, et al. Pediatric pharmacovigilance in an institute of national importance: Journey has just begun. *Indian JPharmacol*.2017;49: 390–5.
- [2]. World Health Organization. Disease and injury country estimates. Available at [http://www.who.int/healthinfo/global\\_burden\\_disease/estimates\\_country/en/index.html](http://www.who.int/healthinfo/global_burden_disease/estimates_country/en/index.html). Accessed 12 February 2012.
- [3]. Anne B Chang, Christina C Chang, K O Grady, P J Torzillo. Lower respiratory tract infections. *Pediatr Clin N Am* 2009;56:1303-21.
- [4]. Nousheen Fatima, Nuzath Fatima, Amatul Jaleel Sameena, Syed Aamir Ali, et al. Study on Adverse Drug Reaction in the Pulmonology Department of a Tertiary Care Hospital. *International Journal of Pharmaceutical Research and Applications*, Volume 8, Issue 3 May-June 2023, pp: 2697-2702
- [5]. Palanisamy S: Study on assessment, monitoring, documentation and reporting of adverse drug reactions at a multi-specialty tertiary care teaching hospital in south India. *International Journal of Pharm Tech Research* 2009;1(4):1519-22.
- [6]. Mohammed Zabeer, Taher Kagalwala, Nousheen Fatima Study on Adverse Drug Reaction in the Pulmonology Department of a Tertiary Care Hospital *Pharmacy Practice*. *ijpra* ,Volume 8, 2023, pp: 2697-2702.
- [7]. Gholami K, Kamali E, Hajiabdolbagh Mi, Shalviri G. Evaluation of antituberculosis