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RESEARCH ARTICLE
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TO STUDY THE ADVERSE DRUG REACTION MONITORING OF COMMONLY PRESCRIBED FIRST LINE ANTITUBERCULAR DRUGS IN PATIENTS AT RAMA MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, KANPUR.

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Abstract:

Background: Tuberculosis (TB) remains a significant public health concern in India, and the first-line antitubercular drugs (ATDs)—Isoniazid, Rifampicin, Pyrazinamide, Ethambutol, and Streptomycin—form the cornerstone of TB treatment. However, these drugs are associated with a range of adverse drug reactions (ADRs), which may affect treatment adherence and outcomes. This study aims to monitor and evaluate the ADRs associated with first-line ATDs among patients receiving treatment at Rama Medical College, Hospital & Research Centre, Kanpur.

Objectives:

1. To identify and categorize adverse drug reactions associated with first-line antitubercular therapy.
2. To assess the incidence, severity, and causality of reported ADRs.
3. To promote awareness about pharmacovigilance among healthcare providers.

Methods:

A prospective observational study was conducted over a specified period among TB patients receiving first-line antitubercular drugs at the Department of Pulmonology and Internal Medicine. Patients were monitored regularly through clinical evaluation, laboratory investigations, and follow-up visits. ADRs were documented, categorized by system organ class, and assessed for severity (using Hartwig's Scale) and causality (using WHO-UMC and Naranjo algorithms).

Results:

Preliminary data indicate a significant incidence of ADRs, with hepatotoxicity, gastrointestinal disturbances, and hypersensitivity reactions being the most commonly reported. Most reactions were mild to moderate in severity, with a few requiring modification or discontinuation of therapy. The majority of ADRs were deemed "possible" or "probable" in causality assessments.

Conclusion:
This study has been done on adverse drug monitoring on different classes of first line antitubercular drugs showing type A, mild, possible, non-serious type of adverse drugs effects has been monitored and most of the patients are recovered.

Keywords: Tuberculosis, Antitubercular Drugs, Adverse Drug Reactions, Pharmacovigilance, First-line Therapy, Kanpur

Introduction:
Adverse drug reaction (ADR) defined as harmful or unpleasant reaction due to the use of a drugs and it may cause different types of effects such as side effects [1] According to the World Health Organization (WHO) adverse drug effects is defined as a response to medicine which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function' [2]

Types of Adverse Drug Effects – [3]
They are two different types of adverse drug effects they are
1. Dose-dependent (also called Type A, Augmented, Predictable)
2. Dose-independent (Type B, Bizarre, Unpredictable, Idiosyncratic)

Factors that can cause Adverse Drug Reactions: - [4]
Adverse drug effects can be categorized they are
1. Patient-related factors – Age, sex, pregnancy, and renal functions
2. Drug-related factors – Drug dose, frequency of administration and time of administration.
3. Disease-related factors – if you are treating disease by using drugs such drugs causes adverse drug effects.
E.g. Using NSAIDS to treat pain may cause a peptic ulcer; a patient with asthma may worsen if he is treated with propranolol for angina or hypertension.
4. Social factors – Smoking. Alcohol and race.

Pharmacovigilance:
According to **WHO** Pharmacovigilance (PV) is defined as the pharmacological science relating to the detection, evaluation, understanding and prevention of adverse effects, particularly long term and short-term side effects of medicines [5].
Pharmacovigilance is important in clinical research both in clinical trials safety and in post marketing. [6] In India Pharmacovigilance started from 1986, Adverse drug reactions (ADR) monitoring was started in 12 regional centers covering population of 50 million. India joined WHO and adverse drug effects in 1997 [7].

Material and Methods:
Study Design: Study was conducted in department of Pharmacology in associated with TB & Chest Rama hospital & research Centre Mandhana Kanpur
Sample Size: Total of 60 Patients.
Study Duration: Study duration was conducted for a period of 1year.
Source of Data: Data was collected from the patients attending OPD/IPD TB and Chest departments during the study period in Rama Hospital Mandhana, Kanpur.
1. Spontaneous ADR reporting technique was used for data collection
2. By reviewing case sheets or treatment charts and investigation reports
3. By interviewing with patients or patient's attendant.
4. By discussing with healthcare professionals.

Adverse drug reaction will be reported in ADR reporting form provided by Indian Pharmacopoeia commission. Patients will be asked in detail about adverse drug reactions. ADR monitoring was done in a systematic manner adopting both spontaneous and intensive monitoring approaches.

Inclusion criteria:

1. Patients of both gender attending IPD/OPD of TB and Chest departments and taking treatment for first line Antitubercular drugs.
2. Patients who will give written informed consent.
3. Patients who is willing to give information about ADR
4. Patients already taking anti-tubercular drugs from last 1 year

Exclusion criteria:

1. Pregnant and lactating females.
2. Patients unable to answer to verbal questions.
3. Patients taking antitubercular drugs and any other medications.
4. Patients taking second line antitubercular drugs.

Result:

The present study is on adverse drug effects on first line Antitubercular drugs were conducted in department of pharmacology in association with department of TB& Chest. Rama Medical College, Hospital & Research Centre, Kanpur.

The data was collected on 60 patients were prescribed with antitubercular drugs conducted over a period of 1 year.

Table No 1: Tabular column represents the gender of patients prescribed with antitubercular drugs.

Gender	No. of patients prescribed with antimicrobial drugs	% of patients prescribed with antimicrobial drugs
Male	40	66.66%
Female	20	33.33%
Total No of patients	60	100%

Figure No 1: Graphical representation of percentage in gender

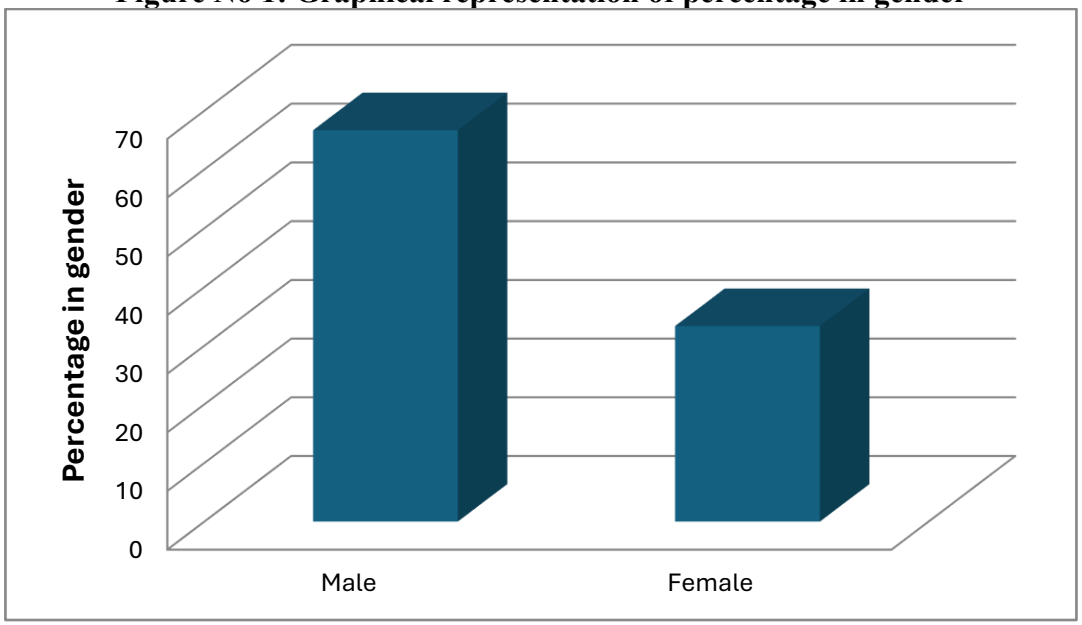


Table No 2: Tabular column represents the age of patients prescribed with antitubercular drugs

S.No	Age Ranges	No. of Patients	Percentage
1	30 – 40	23	38.33 %
2	41 – 50	20	33.33 %
3	51 – 60	11	18.33 %
4	61 – 70	02	03.33 %
5	71 – 80	04	6.66 %
	Total	60	100 %

Figure No 2: Graphical representation of age of antitubercular patients.

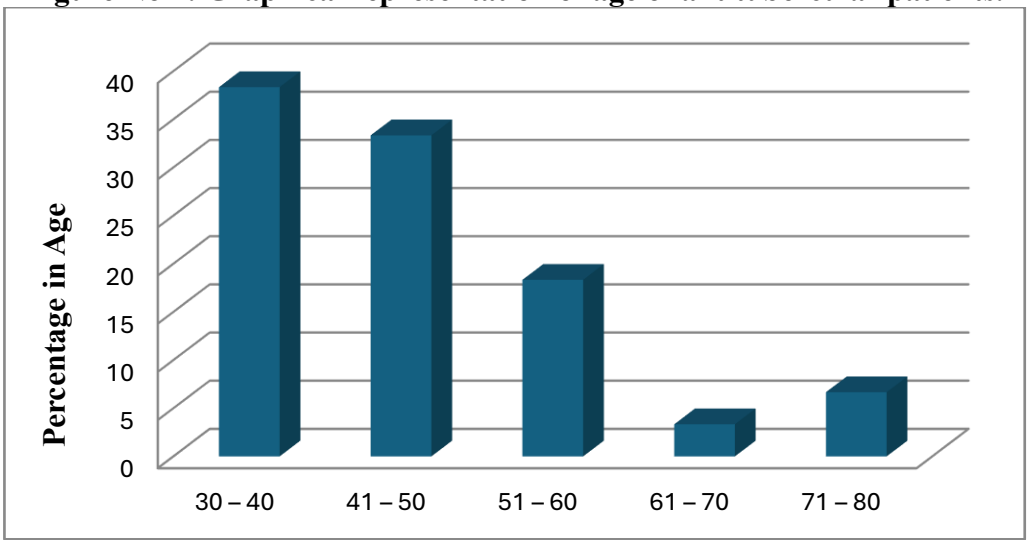


Table No 3: Tabular column represents the antitubercular drugs prescribed to the patients.

S.No	Drugs	No of patients prescribed with antitubercular drugs	Percentage
1	Isoniazid	38	63.33%
2	Rifampicin	12	20 %
3	Pyrazinamide	06	10 %
4	Ethambutol	04	6.66 %
	Total	60	100%

Figure No 3: Graphical representation of percentage prescription of antitubercular drugs.

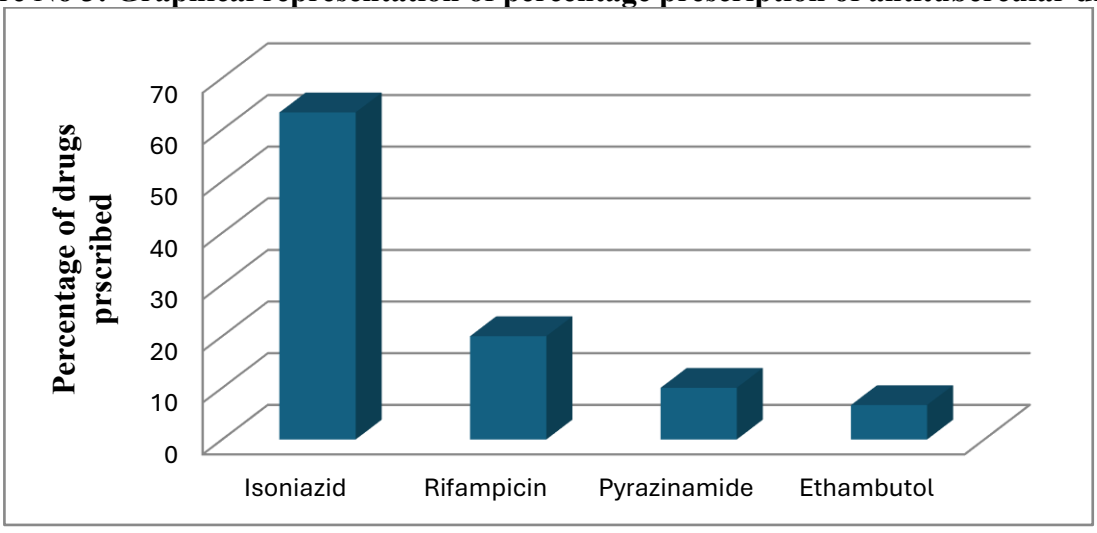


Table No 4: Tabular column represents the types of ADRs reported in patients prescribed with antitubercular drugs.

S.No	Type of ADRs	No of patients prescribed with antimicrobial drugs	Percentage
1	Type A	42	70 %
2	Type B	12	20 %
3	Type C	06	10 %
4	Type D	-	-
5	Type E	-	-
6	Type F	-	-
	Total	60	100 %

Figure No 4: Graphical representation of type of ADR reported in patients prescribed with antitubercular drugs.

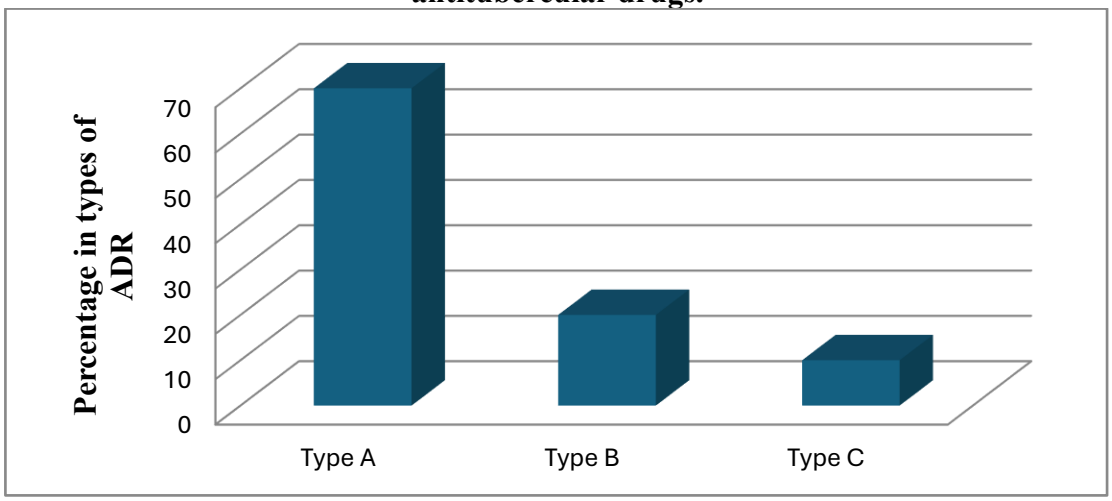


Table No 5: Tabular column represents the Severity Scale reported in patients prescribed with antitubercular drugs

S.No	Type of Severity	No of patients	Percentage
1	Mild	38	63.33 %
2	Moderate	18	30 %
3	Severity	04	6.66 %
	Total	60	100 %

Figure No 5: Graphical representation of severity scale in patients prescribed with Antitubercular drugs.

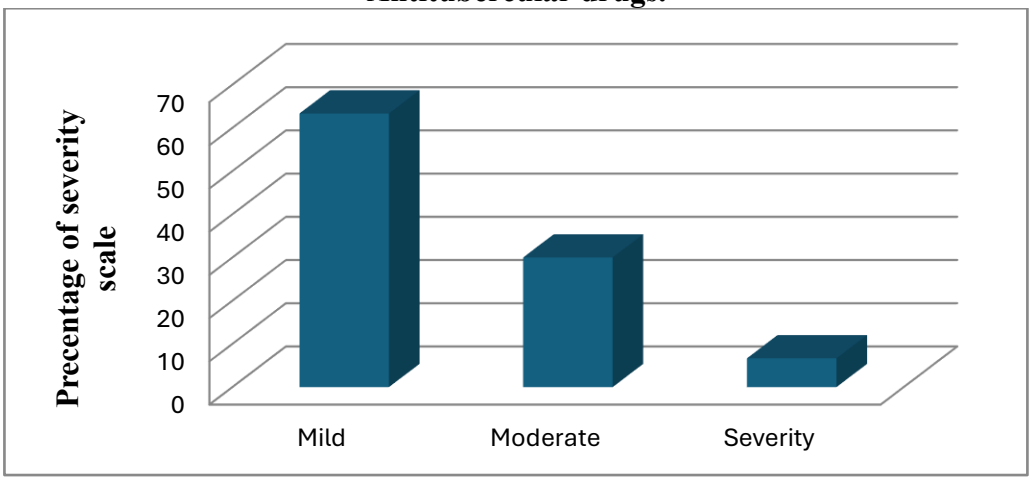


Table No 6: Tabular column represents the Causality Assessment reported in patients prescribed with antitubercular drugs

S.No	Causality Assessment	No of Patients	Percentage
1	Certain	-	-
2	Probable	11	18.33 %
3	Possible	46	76.66 %
4	Unlikely	03	5 %
Total		60	100 %

Figure No 6: Graphical representation of causality assessment in patients prescribed with antitubercular drugs.

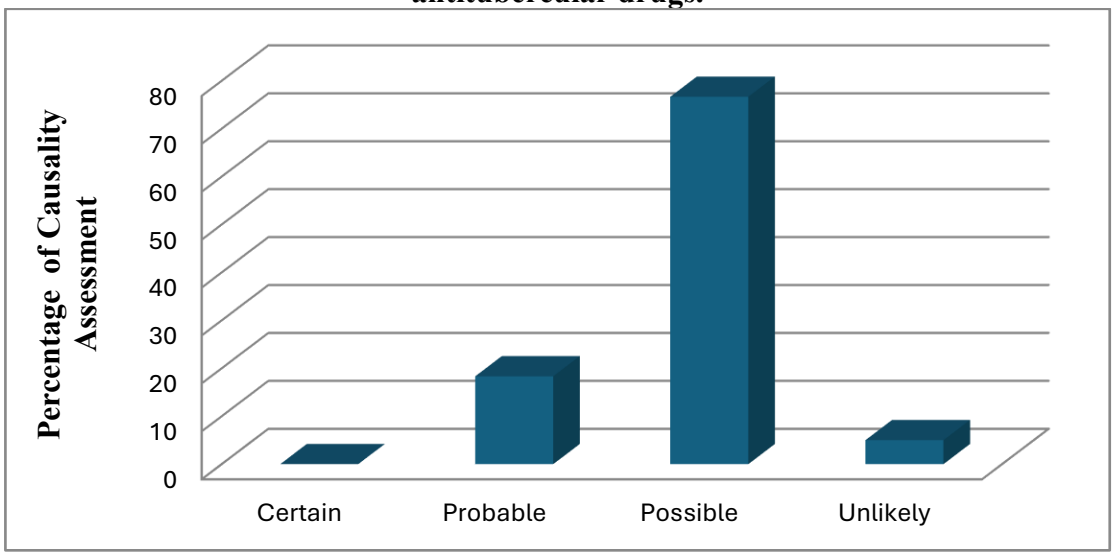


Table No 7: Tabular column represents the Seriousness reported in patients prescribed with antitubercular drugs

S.No	Seriousness	No of Patients	Percentage
1	Serious	03	5 %
2	Non-serious	57	95%
3	Severe	-	-
Total		60	100 %

Figure No 7 : Graphical representation of seriousness in patients prescribed with antitubercular drugs.

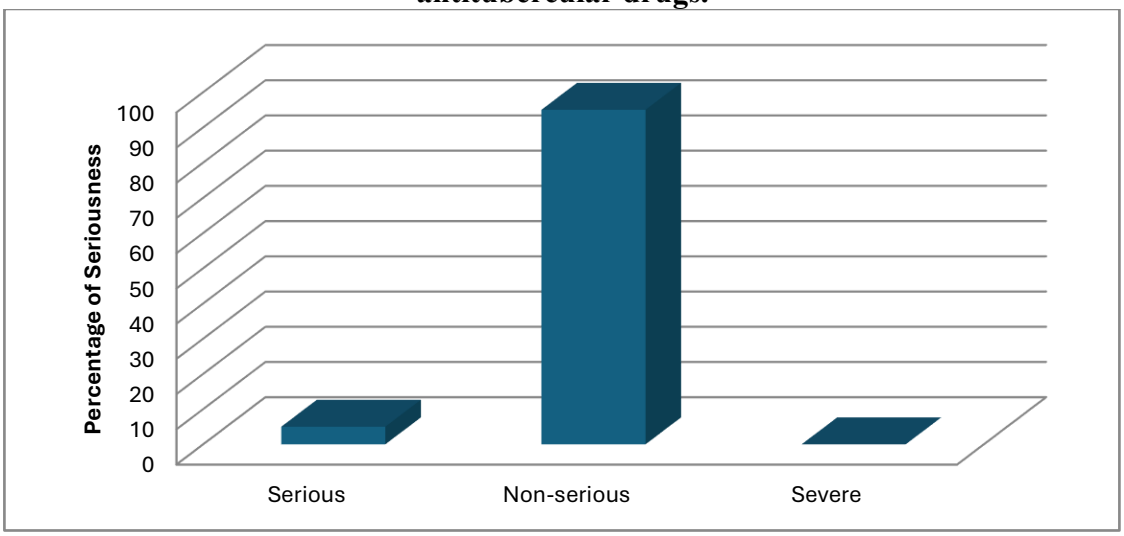
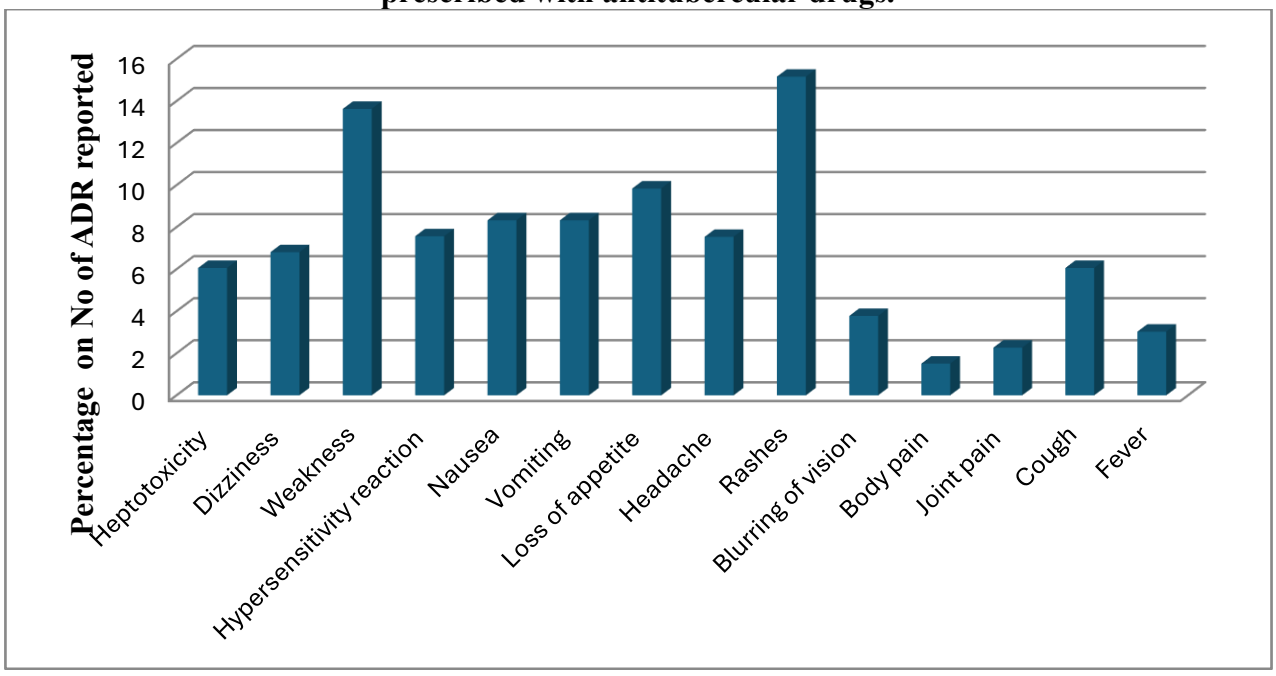


Table No 8: Tabular column represents the No of ADR reported in patients prescribed with antitubercular drugs

ADR reported	No of ADR reported	Percentage
Heptotoxicity	08	6.06%
Dizziness	09	6.81 %
Weakness	18	13.63 %
Hypersensitivity reaction	10	7.57%
Nausea	11	8.33%
Vomiting	11	8.33%
Loss of appetite	13	9.84 %
Headache	10	7.57 %
Rashes	20	15.16 %
Blurring of vision	05	3.78%
Body pain	02	1.51%
Joint pain	03	2.27%
Cough	08	6.06%
Fever	04	3.03%
Total	132	100%

Figure No 8: Graphical representation of Number of adverse drug effect observed in patients prescribed with antitubercular drugs.



Discussion: Tuberculosis is a respiratory disease caused by mycobacterium, is a acid fast bacilli causing an infectious disease leading to death. This infection is mostly seen in lungs, also affects all the organs. As it is respiratory disease gets transmitted by droplet of TB patients.

This study was conducted on 60 patients suffering from tuberculosis prescribed with first line different antitubercular drugs. There are 58.33% male and 41.66% females were observed and among age group range between 51-60 there are 23 patients 38.33% observed higher in this study.

This study was conducted on 60 patients suffering from tuberculosis prescribed with first line different antitubercular drugs. There are 66.66% male and 33.33% females were observed and among age group range between 30 -40 there are 23 patients 38.33% observed higher in this study. These studies coincide with the study of Manju et al. (2020)

Conclusion: Pharmacovigilance is a branch that deals with the adverse drug effects, monitoring of adverse drug effects of different classes of drugs are essential to prevents complication due to prolonged use of drugs.
This study has been done on adverse drug monitoring on different classes of first line antitubercular drugs showing type A, mild, possible, non-serious type of adverse drugs effects has been monitored and most of the patients are recovered.

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