

CLINICAL PROFILE MEDICATION ADHERENCE AND ADVERSE DRUG REACTIONS OF ANTI-TB DRUGS IN DEPARTMENT OF PULMONARY MEDICINE IN A TERTIARY CARE HOSPITAL

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Abstract-

INTRODUCTION

Tuberculosis is a chronic infections disease caused by Mycobacterium tuberculosis and occasionally by Mycobacterium bovis and Mycobacterium africanum. It particularly affects the lung which is called pulmonary TB. There is increased incidence of tuberculosis in HIV positive patients but it can affect other sites as well. TB accounts for more than 10 million cases and 1.3 million deaths. Adherence to TB drugs is critical in achieving successful treatment outcomes controlling the spread and preventing the development of drug resistance non-adherence to treatment refers to a patient's inability or refusal to take TB medications as prescribed by a health professional. Non-adherence to Antituberculosis treatment adversely affects treatment success rate. It increases morbid and mortality. Also, it contributes significantly to the development of drug resistance.

AIMS & OBJECTIVES

To assess the Clinical Profile, Medication Adherence and Adverse Drug Reactions of Anti Tubercular Drugs in Government General Hospital.

OBJECTIVES OF THE STUDY

The key objectives of the study include

To assess the clinical profile of TB patients

To determine the medication adherence

To determine the adverse drug reactions of anti-tubercular drugs.

METHODOLOGY: It is a prospective observational study to be conducted in Government General Hospital Kurnool district in the department of pulmonary medicine.

RESULTS & DISCUSSION: In our present study, 70(57.37%) were males and 52 (42.62%) were females. This study was similar to the study conducted by maheen Humayun et al²⁹ where males were 58.5 & females were 41.5. In our present study of social habits males with smoking are 40(32.7%) and alcoholic are 33(27%). Whereas females with smoking are 5(4.09%) and alcoholic are 4(3.37) and 39(31.9%) patients are diabetic, 44(36%) patients have hypertension, 19(15.5%) patients have thyroid, 16(13.1%) patients have renal problems, 17(13.9%) patients have HIV and 15(12.2%) patients have cardiac problems. The common clinical manifestation is cough with sputum (78.5%) followed with weight loss of (63.49%), loss of appetite (61.1%), fever with night sweats (56.34%), chest pain (44.44%), shortness of breath (46.35%) and blood with sputum (14.28%). In our study most of the patients are non-adhere (31.1%) to the TB medications which may be due to negligence (inadequate knowledge) 25.19% followed by adverse drug reactions (22.13%), below poverty (14.28%) and Physiatric problems (6.55%).

CONCLUSION: The present study was conducted to study the clinical manifestations, medication adherence and adverse drug reactions of TB medications. Tuberculosis has become a public health crisis. In the current study, the sample size was 122; most of them are males constituting 57.37%. The mean age of the study subjects was 65.5 years. Majority of patients was suffering with TB in the age of 50-80 years. Joint pains were the most common ADR constituting 43.41% whereas nephrotoxicity was the least ADR constituting 4.91%. Negligence (inadequate knowledge) was the most common associated barrier to TB medication constituting 25.19% whereas the psychiatric problem (6.555) was the least associated barrier.

Keywords: Naranjo Adverse Drug Reaction Probability Scale, Morisky Medication Adherence scale.

I. INTRODUCTION

Tuberculosis is a chronic infections disease caused by Mycobacterium tuberculosis and occasionally by Mycobacterium bovis and Mycobacterium africanum. It particularly affects the lung which is called pulmonary TB but it can affect other sites as well ⁽¹⁾. TB accounts for more than 10 million cases and 1.3 million deaths ⁽²⁾. Transmission is by droplet nuclei of 1-5m in diameter which deposit on the alveoli. There is increased incidence of tuberculosis in HIV positive patients ⁽³⁾. The Clinical Features of TB are Insidious onset of cough and sputum; initially there are no physical signs, later crackles over lung apex, Signs of consolidation, Cavity or fibrosis develops, Pleural effusion (hypersensitivity reaction) or spontaneous pneumothorax are other types of presentation. Haemoptysis is due to the rupture of hypertrophied bronchial vessel. A blood clot is also caused by erosion of a blood vessel in the wall of the cavity or the formation of an aspergilloma in an old cavity ⁽⁴⁾. The Complications of TB are Hemoptysis, Tubercular bronchiectasis, Fungal ball or Aspergillos, Tubercular endobronchitis and tracheitis, Spontaneous pneumothorax Scar carcinoma, Disseminated calcification of the lungs, Obstructive airway disease Secondary pyogenic infection, Secondary amyloidosis, Respiratory failure, Cor pulmonale ⁽⁵⁾. Adherence to TB drugs is critical in achieving successful treatment outcomes controlling the spread and preventing the development of drug resistance. Completion of 2 months intensive followed by 4 to 7 months continuous phase of therapy has shown to cure most of the Drug sensitive case with only less than 5-8% chances of relapse, whereas non-adherence of TB drugs likely leads to MDR-TB post TB sequel ⁽⁶⁾. Non-adherence to Antituberculosis treatment adversely affects treatment success rate. It increases morbid and mortality. Also, it contributes significantly to the development of drug resistance ⁽⁷⁾.

II. AIM & OBJECTIVES

The aim of the present study is to assess the Clinical Profile, Medication Adherence and Adverse Drug Reactions of Anti Tubercular Drugs in Government General Hospital.

OBJECTIVES

- The key objectives of the study include
- To assess the clinical profile of TB patients
- To determine the medication adherence
- To determine the adverse drug reactions of anti-tubercular drugs.

III.METHODOLOGY

Study Design: Prospective Observational Study.

Study Site: Government General Hospital Kurnool.

Study Population: 122 patients.

Study Duration: The study would be conducted over a period of six months.

Source of Data: Data would be collected from those patients who are admitted in tertiary care hospital in Pulmonary medicine ward who are prescribed with anti-tubercular drugs.

Method of collection of Data: Data collection would be done by using the following documents. Annexure-1(Patient Demographic Data Collection Form), Annexure-2(medication adherence questionnaire form), Annexure-3(Naranjo's scale).

Inclusion Criteria

- All patients diagnosed with TB are included.
- All the patients of either sex aged above 18 years would be included.
- Conscious, co-operative, non-co-operative patients and pregnant woman are included.
- All patients with co-morbid conditions are also included in our study.

Exclusion Criteria

- Pediatric.
- Psychiatric patients with tuberculosis.
- Patients who are not willing to participate in the study.

IV. RESULTS

4.1 Gender wise distribution of subjects

A total of 122 subjects were collected among them 70 are males and 52 are females

Tab.4.1. Gender wise distribution of subjects

Male	Female
70	52

GENDER WISE DISTRIBUTION

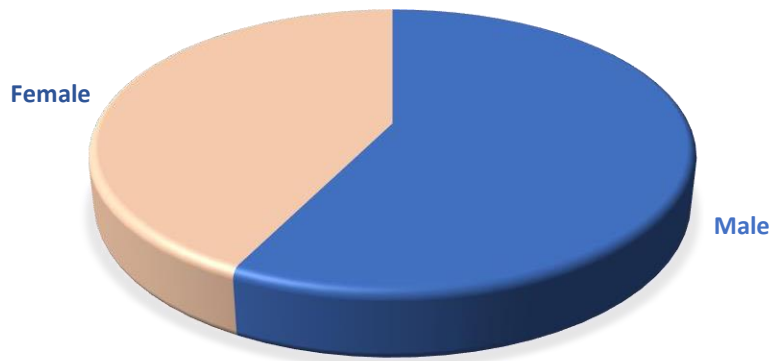


Fig.4.1. GENDER WISE DISTRIBUTION

4.2 Age wise Distribution of subjects

A total no. of 122 subjects were collected among them the age of distribution was as follows- males with age of 18-30 are (11),31-50 are (26),51-80 are (34) and above 80 are (01), whereas females with age of 18-30 are (12),31-50 are (17), 51-80 are (21), and above 80 are (02).

Tab.4.2. Age wise Distribution of subjects

Gender	18-30	31-50	51-80	>80
Male	11	26	34	1
Female	12	17	21	2

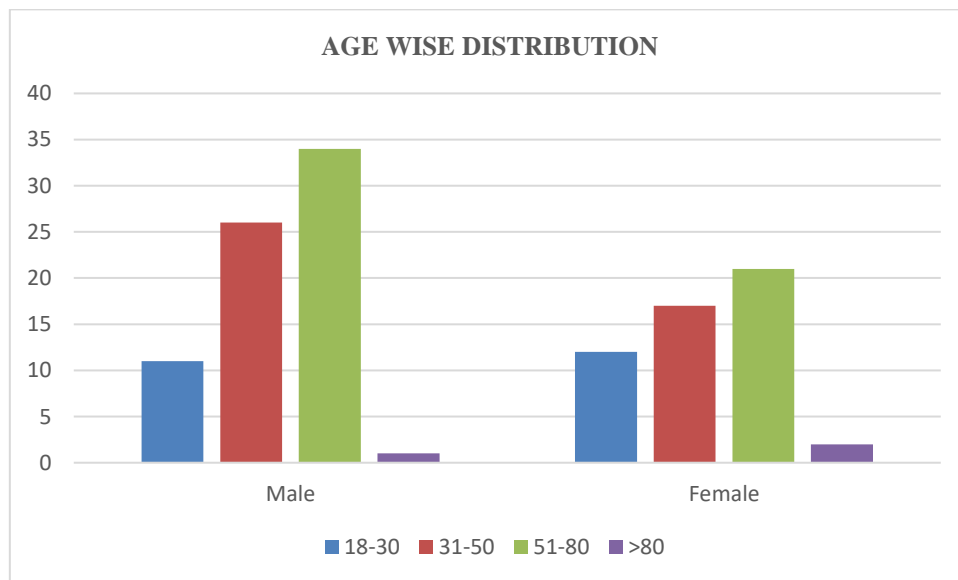


Fig.4.2. Age wise Distribution of subjects

4.3 Distribution of subjects based on their social habits

A total no. of 122 subjects were collected, among them males under alcoholic are 33, smokers are 40 and with both social habits include 28, whereas females under alcoholic are 04, smokers are 05 and with both social habits include 03.

Tab.4.3. Distribution of subjects based on their social habits

Gender	Alcoholic	Smoker	Both
Male	33	40	28
Female	4	5	3

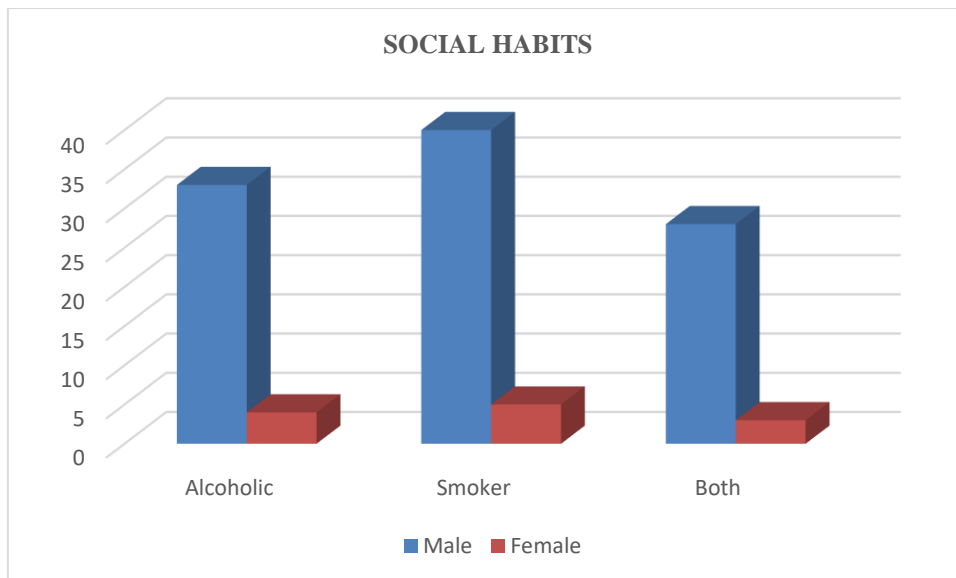


Fig.4.3. Distribution of subjects based on social habits

4.4 Distribution of subjects based on co-morbidities

A total no. of 122 subjects were collected among them males (59) are associated with more co- morbidities than females (28).

Tab.4.4. Distribution of subjects based on co-morbidities

Males	Females
59	28

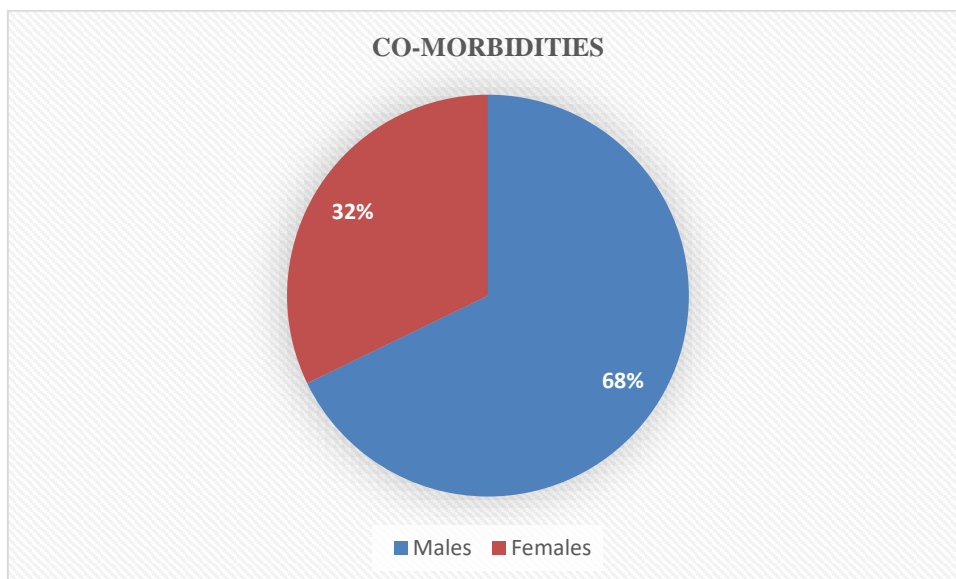


Fig.4.4. Distribution of subjects based on co-morbidities

4.5 Distribution of subjects based on types of co-morbidities

A total no. of 122 subjects were collected among them HTN is the most common co-morbidity in both males (31) and females (13), following with Diabetes (M-27, F-12), Thyroid (M-08, F-11), Renal (M- 10, F- 06), HIV (M- 08, F- 07) and Cardiac (M-10, F-05).

Tab.4.5. Distribution of subjects based on types of co-morbidities

Co-morbidities	Males	Females
Diabetes	27	12
Hypertension	31	13
Thyroid	08	11
Renal	10	06
HIV	08	07
Cardiac	10	05

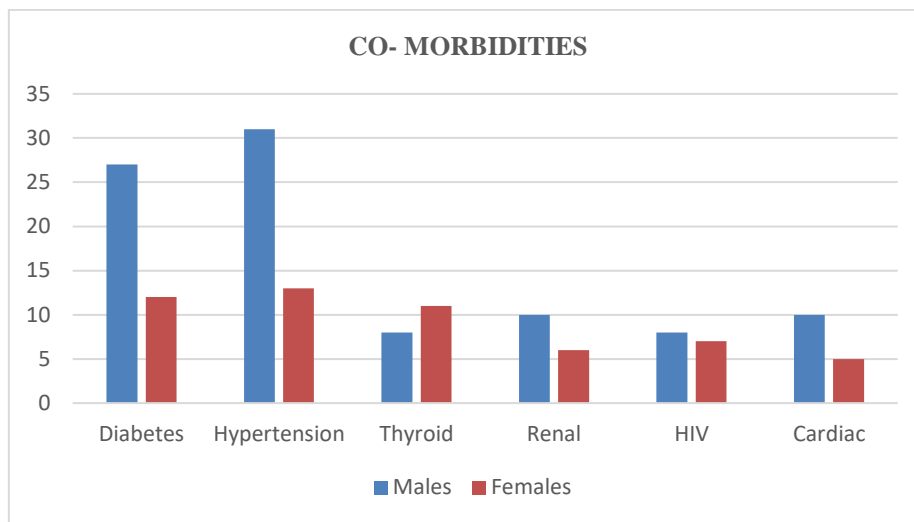


Fig.4.5. Distribution of subjects based on types of co-morbidities

4.6 Distribution of subjects based on marital status

A total no. of 122 subjects were collected among them 64 males and 44 females are married whereas 06 males and 03 females are unmarried and 03 females are divorced.

Tab.4.6. Distribution of subjects based on marital status

Gender	Married	Unmarried	Divorced
Males	64	6	0
Females	44	3	3

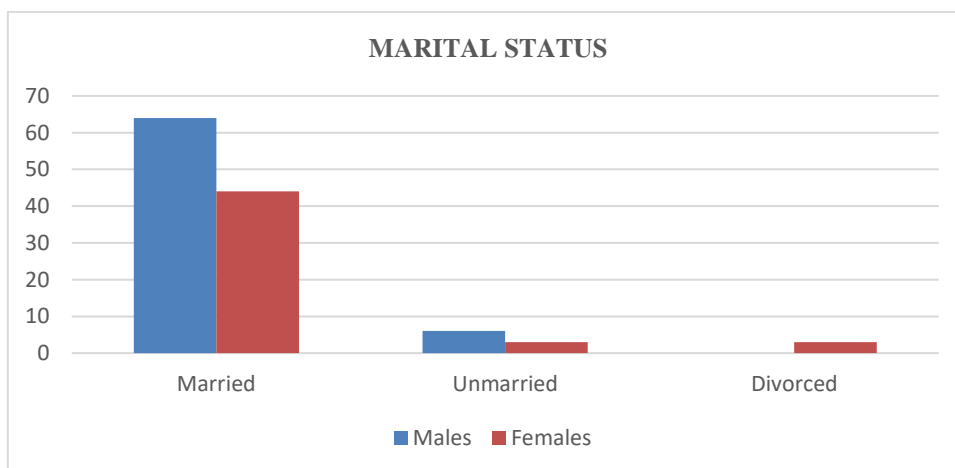


Fig.4.6. Distribution of subjects based on marital status

4.7 Distribution of subjects based on Educational status

A total no. of 122 subjects were collected among them 10 males and 12 females are literate whereas 60 males and 38 females are illiterate.

Tab.4.7. Distribution of subjects based on educational status

Gender	Literate	Illiterate
Males	10	60
Females	12	38

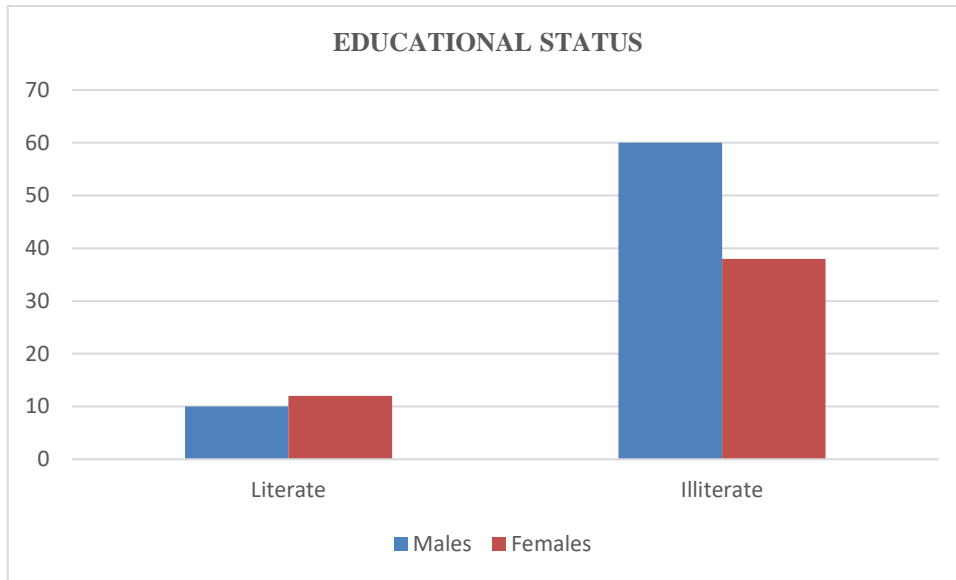


Fig.4.7. Distribution of subjects based on educational status

4.8 Distribution of subjects based on Disease type

A total no. of 122 subjects were collected among them 59 males and 39 females were diagnosed with pulmonary TB whereas 11 males and 12 females with extra-pulmonary TB.

Tab.4.8. Distribution of subjects based on Disease type

Gender	Pulmonary TB	Extra Pulmonary TB
Males	59	11
Females	39	12

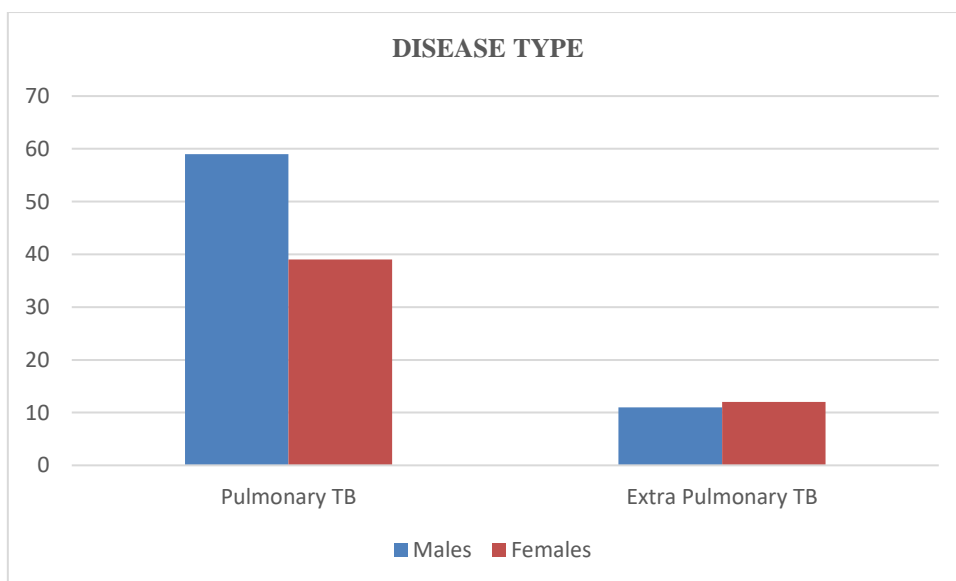


Fig.4.8. Distribution of subjects based on Disease type

4.9 Distribution of subjects based on type of extra pulmonary TB

A total no. of 122 subjects were collected among 03 males and 03 females are diagnosed with GIT TB, 05 males and 03 females with CNS (Meningeal) TB and 03 males and 06 females with Lymphatic TB.

Tab.4.9. Distribution of subjects based on type of extra pulmonary TB

Gender	GI	CNS	Lymph Nodes
Males	3	5	3
Females	3	3	6

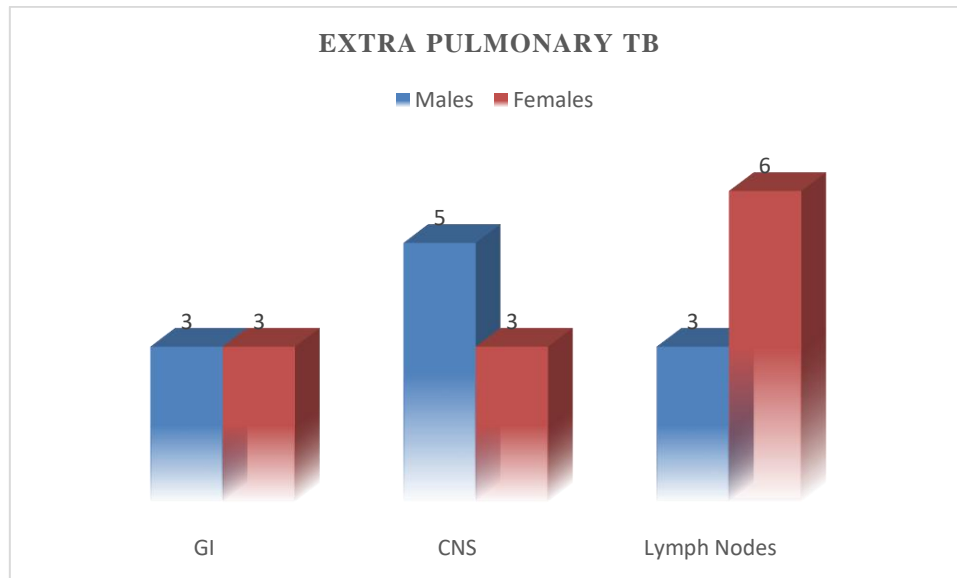


Fig.4.9. Distribution of subjects based on type of extra pulmonary TB

4.10 Distribution of subjects based on clinical manifestation

A total no. of 122 subjects were collected among them most of the subjects were suffered with cough with sputum (78.57%), followed with weight loss (63.49%), loss of appetite (61.11%), fever with night sweats (56.34%), chest pain (44.44%), SOB (43.65%) and blood with sputum (14.28%).

Tab.4.10. Distribution of subjects based on clinical manifestation

CLINICAL SYMPTOMS	Patients	Percentage (%)
Cough with sputum	99	78.57%
Blood with sputum	18	14.28%
Fever with night sweats	71	56.34%
Weight Loss	80	63.49%
Loss of appetite	77	61.11%
SOB	55	43.65%
Chest pain	56	44.44%

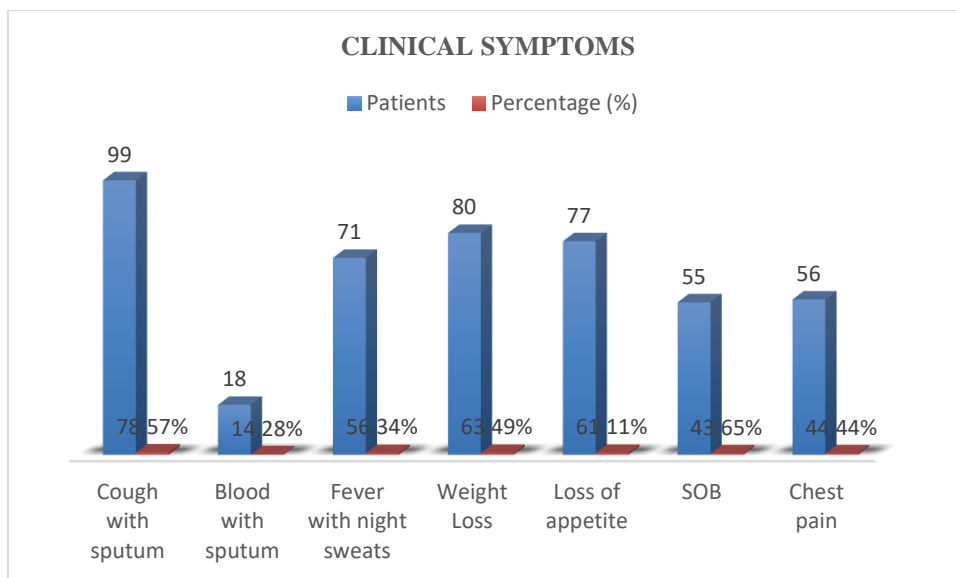


Fig.4.10. Distribution of subjects based on clinical manifestation

4.11 Gender wise Distribution of subjects based on MORISKY Medication Adherence scale

A total no of 122 subjects were collected among them low adherence was seen in 38 males 41 females whereas moderate adherence 20 males and 29 females and high adherence was found in 11 males and 16 females.

Tab.4.11. Gender wise Distribution of subjects based on MORISKY Medication Adherence scale

Score	Males	Female
Low Adherence	38	41
Moderate Adherence	20	29
High Adherence	11	16

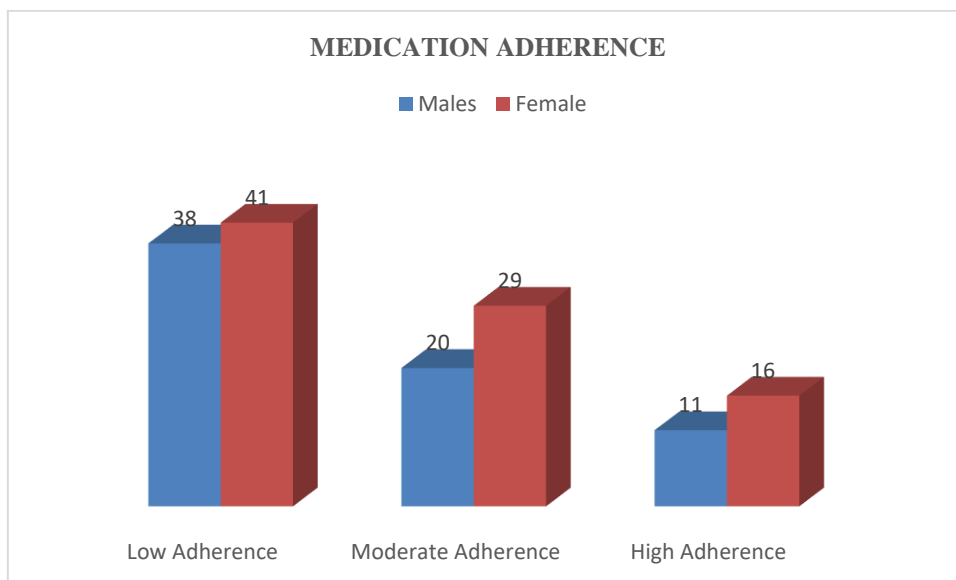


Fig.4.11. Gender wise Distribution of subjects based on MORISKY Medication Adherence scale

4.12 Distribution of Medication Adherence by Age wise among Males

Tab.4.12. Distribution of Medication Adherence by Age wise among Males

Score	18-30	31-50	51-80	>80
Low Adherence	7	13	18	0
Moderate Adherence	2	10	9	0

High Adherence	2	2	7	0
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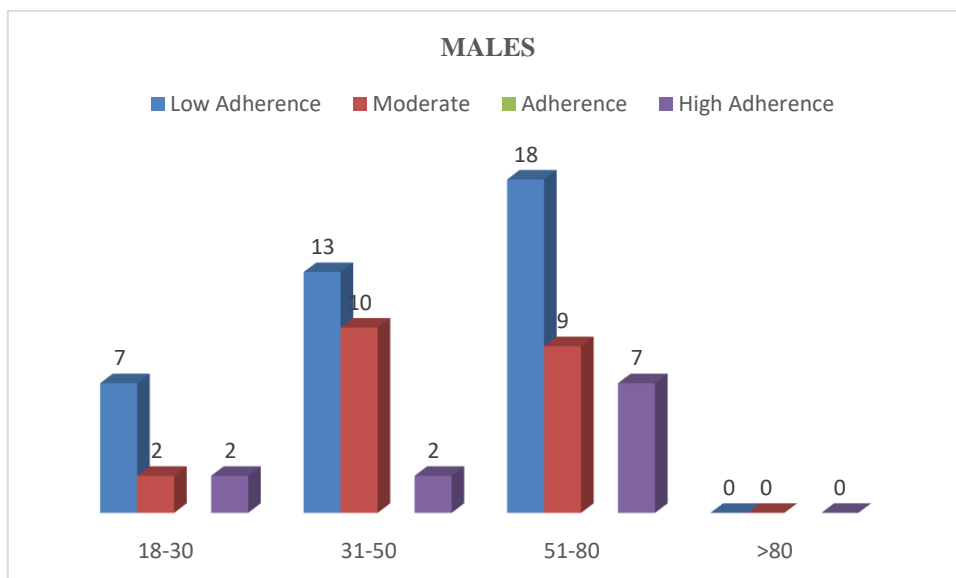


Fig.4.12. Distribution of Medication Adherence by Age wise among Males

4.13 Distribution of Medication Adherence by Age wise among Females

Tab.4.13. Distribution of Medication Adherence by Age wise among Females

Score	18-30	31-50	51-80	>80
Low Adherence	6	9	9	1
Moderate Adherence	4	5	6	0
High Adherence	2	3	3	0

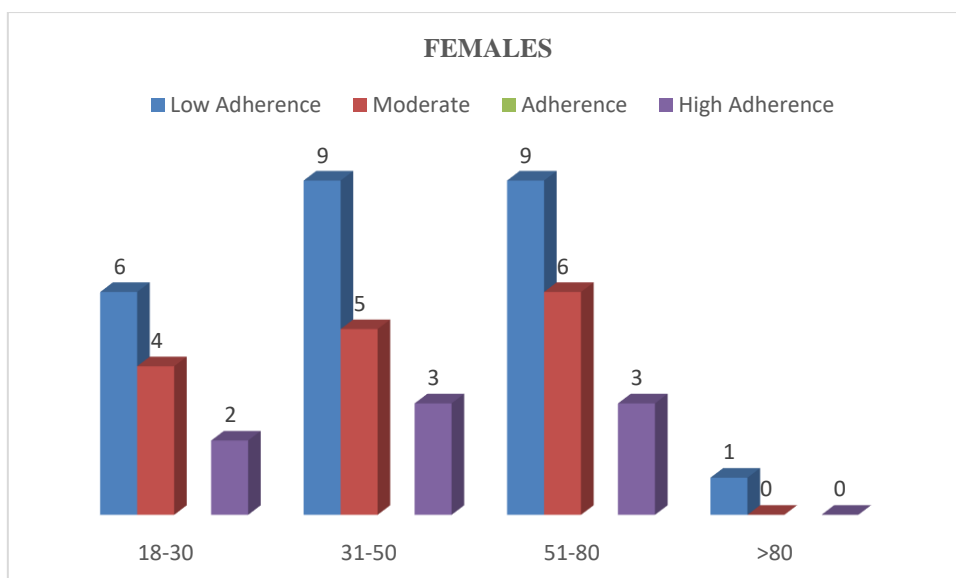


Fig.4.13. Distribution of Medication Adherence by Age wise among Females

4.14. Reasons for nonadherence

A total no. of 122 subjects were collected among them the subjects with nonadherence in males due to adverse drug reactions are 19 where as in females are 08, due to poverty are 03 in males and 05 in females, whereas due to negligence are 21 in males and 09 in females, with psychiatry problem are 03 in males and 05 in females.

Tab.4.14. Reasons for nonadherence

Reasons	Males	Females
Adverse drug reaction	19	8
Poverty	3	5
Negligence	21	9
Psychiatric problem	3	5

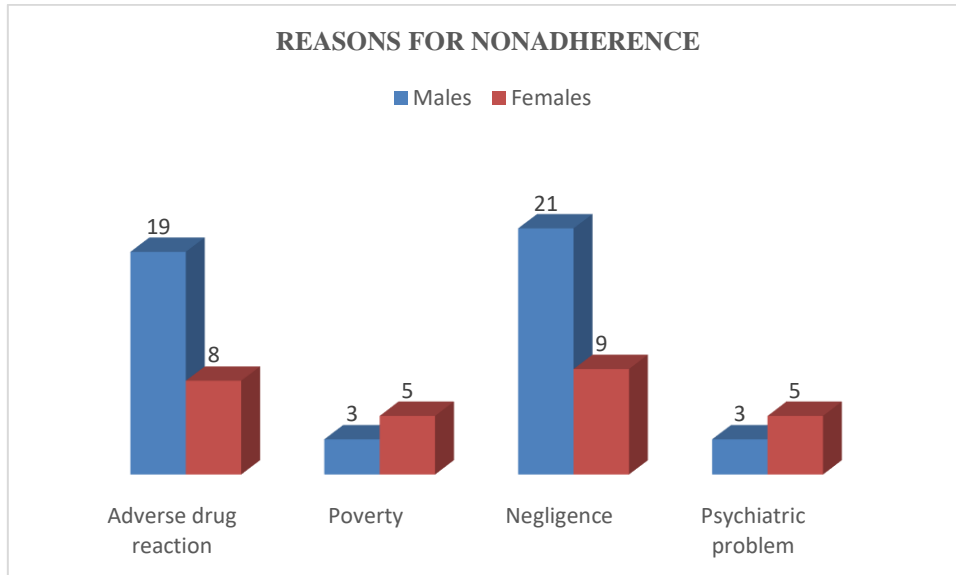


Fig.4.14. Reasons for nonadherence

4.15 Gender Wise Distributions of Adverse Drugs Reactions

A total of 122 subjects were collected among them ADRS are seen in males (46) and females (31).

Tab.4.15. Gender Wise Distributions of Adverse Drugs Reactions

Adverse Drug Reactions	Males	Females
Adverse drug reactions	46	31

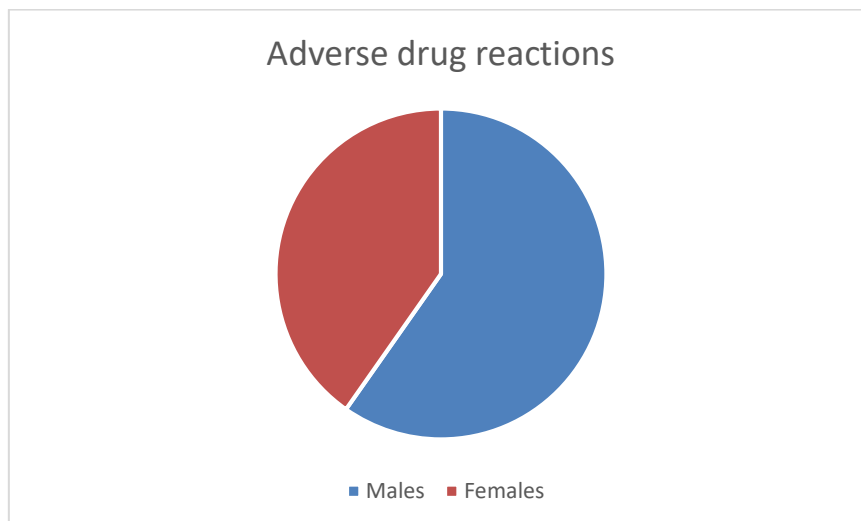


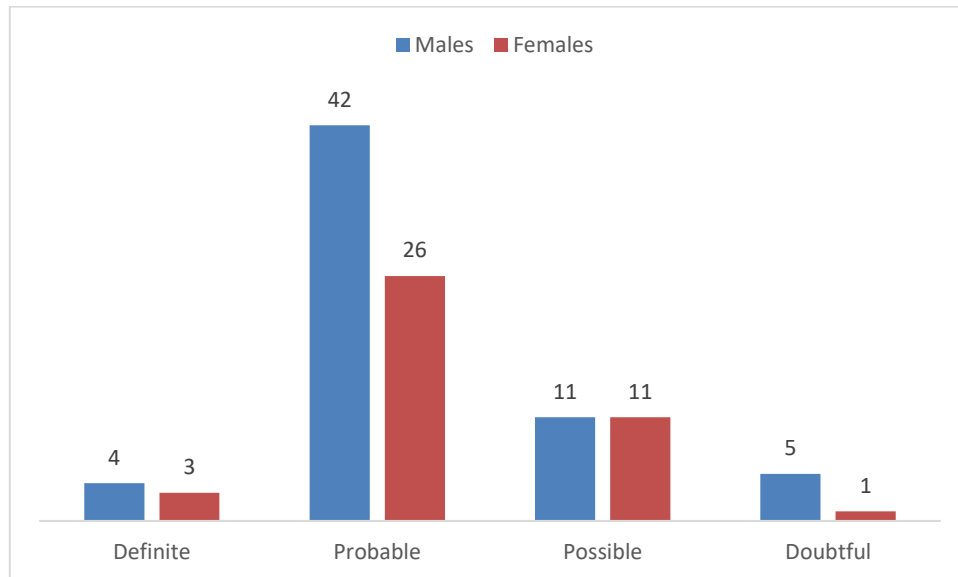
Fig.4.15. Gender Wise Distributions of Adverse Drugs Reactions

4.16 Distribution of ADR by Naronjo Scale

A total of 122 subjects were collected among them the definite ADR score was seen in 4 males and 3 females and probable ADR score was seen in 42 males and 26 females and possible ADR score was seen in 11 males and 11 females and Doubtful ADR score was seen in 5 males and 1 in females

Tab.4.16. Distribution of ADR by Naronjo Scale

Probability of ADR	Males	Females
Definite	4	3
Probable	42	26
Possible	11	11
Doubtful	5	1

**Fig.4.16. Distribution of ADR by Naronjo Scale****4.17 Gender wise Distribution of Type of Adverse Drug Reactions****Tab.4.17. Gender wise Distribution of Type of Adverse Drug Reactions**

Type of ADR	Males	Females
Diarrhea	18	7
Dizziness	19	19
Vomiting	31	18
Decreased Appetite	23	19
Throat Irritation	13	6
Anemia	8	9
Mouth Ulcers	9	6
Ototoxicity	0	0
Nephrotoxicity	2	0
Seizures	4	2
Peripheral neuropathy	2	2
Psychological Depression	6	3
Body and Joint Pains	30	23
Fever	5	1

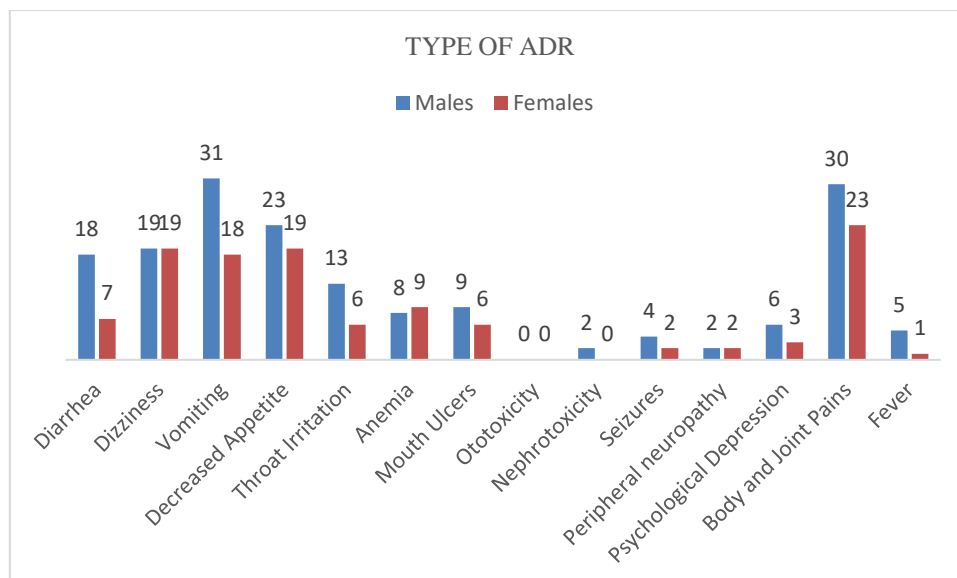


Fig.4.17. Gender wise Distribution of Type of Adverse Drug Reactions

5. DISCUSSION

A Prospective observational study was conducted for 6 months in a tertiary care teaching hospital in department of pulmonary medicine at Government general hospital, Kurnool. A total of 122 subjects were studied who comes under inclusive criteria.

- In the present study, 70(57.37%) were males and 52 (42.62%) were females. This study was similar to the study conducted by maheen Humayun et al²⁹ where males were 58.5 & females were 41.5.
- In similar studies done by Suresh Rao et al³⁰ males were 69% & females were 31%. The incidence of Tuberculosis itself is more in males when compared to females. As males are exposed to outside society, more in contact in peer group, they have greater chance of acquiring the disease and moreover, females won't come up with the disease because of social stigma.
- In the current study age was ranging from the highest of 70 to the lowest of 18, 23(18.85%) were in the age group of 18-30, 43 (35.24%) were in the age group of 31-50, 55(45.08%) were in the age group of 51-80, 3(2.45%) were in the age group of >80. More no. of patients was in the age group of 51-80. Mean age of the present study was 65.5 almost similar to the mean age of 69.25 in the study conducted by murray et al mean age was 29.05.
- In the present study of social habits males with smoking are 40(32.7%) and alcoholic are 33(27%). Whereas females with smoking are 5(4.09%) and alcoholic are 4(3.37), which is similar to the study conducted by Rao VG et al where males have greater percentage in social habits compared to females. In the study conducted by Jayadeepatra et al similar results are seen when compared to the present study.
- Outcome was poor in patients with co morbid conditions. In the present studies 39(31.9%) patients are diabetic, 44(36%) patients have hypertension, 19(15.5%) patients have thyroid, 16(13.1%) patients have renal problems, 17(13.9%) patients have HIV and 15(12.2%) patients have cardiac problems which is similar to the study conducted by Bibha Maraket al where HTN(24.5%) is the most common co morbid condition followed by Diabetes (7.5%) among patients. In the study conducted by Cox Se et al where (19%) patients have HTN, (22%) have diabetes which is contrast to our present study. In the study conducted by Segafredo G et al HTN (19.4%) is the most common co morbidity similar to our present study.
- In our study lymphadenitis (10.19%) is the most common EPTB followed by GI which is similar to the study conducted by peto et al. In the study conducted by Mathew R Weir, similar results were found where lymphadenitis (37%) is the most common type of EPTB.
- In the present study patients with cough with sputum (78.5%) followed with weight loss of (63.49%), loss of appetite (61.1%), fever with night sweats (56.34%), chest pain (44.44%), shortness of breath (46.35%) and blood with sputum (14.28%). In the study conducted by acharya et al cough with expectoration (60%) were most common presenting symptom which is similar to our present study. In the study conducted by Chowdary et al fever (37%) was the most common symptom which is contrast to our present study.
- In the present study most of the patients are non-adhere (31.1%) to the TB medications which are similar to the study conducted by P Y Kulkarni et al where 45% are non-adhere to the TB medications.
- In the study conducted by Sungho Bea et al 56% were adhere to the TB medication which is contrast to our present study.

- In the present studies most of the patients were non adhere to the TB medication due to negligence (inadequate knowledge) 25.19% followed by adverse drug reactions (22.13%), below poverty (14.28%) and Physiatriac problems (6.55%) which are similar to the study conducted by Herrero et al where negligence (30%) is the most common barrier to medication adherence followed by poverty (20%).
- In the study conducted by Bhattacharya et al adverse drug reaction (40%) is the most common cause which is contrast to our present study.
- In our study most of the subjects are illiterate that results in the inadequate knowledge regarding medication when compared to the study conducted by Bhattacharya et al where subjects are literate.
- In the present study joint pains (43.41%) rea the most common ADR followed by vomiting (40.1%) and others which are similar to the study conducted by Ramesh et al where joint pains (41%) are most common ADR.
- In the study conducted by mirunalini Ravichandran et al vomiting (39%) is the most common ADR which is contrast to our present study.

6. CONCLUSION

- The present study was conducted to study the clinical manifestations, medication adherence and adverse drug reactions of TB medications.
- Tuberculosis has become a public health crisis.
- In the current study, the sample size was 122, most of them are males constituting 57.37%.
- The mean age of the study subjects was 65.5 years. Majority of patients was suffering with TB in the age of 50-80 years.
- Social habits (Alcohol. Smoking) were most commonly seen in males constituting 32% and 27%.
- Co morbidities were most commonly seen in males associated with 48.36%
- Hypertension was the most commonly associated co morbidity constituting 36%. Least commonly associated co morbidity was renal disease.
- Most of the subjects were illiterate under males constituting 49.1%.
- Pulmonary TB was most common in males constituting 48.3% whereas extra pulmonary TB was least in females constituting 9.83%.
- Lymphadenitis was the most common Extra pulmonary TB constituting 10.19%. Least commonly Extra pulmonary TB was gastrointestinal TB.
- Cough with sputum was the most commonly observed clinical manifestation constituting 78.5%. Least clinical feature was found to be blood with sputum constituting 14.28%.
- Low adherence was most commonly seen in females constituting 33.60% under the age of 51-80 years.
- 31.1% subjects were nonadherence to TB medication where as 9.01% were adherence to TB medication.
- Adverse drug reactions were most commonly seen in males constituting 37.70% where probable of ADR is more in males and females constituting 34.42% and 21.31% according to ADR Naranjo scale.
- Joint pains were the most common ADR constituting 43.41% whereas nephrotoxicity was the least ADR constituting 4.91%.
- Negligence (inadequate knowledge) was the most common associated barrier to TB medication constituting 25.19% whereas the psychiatric problem (6.555) was the least associated barrier.

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