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**Original Research Article** 

# Observational study on Drug Resistance TB among patients with New Sputum Smear Positive Pulmonary Tuberculosis- in Tertiary care centre

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#### Abstract

Aim& Objective: This study mainly focuses on the detection, comparison of prevalence of MDR-TB among New smear sputum Positive TB patients. And To determine the pattern of drug resistance in them. Methodology: 100 cases of new smear positive TB patients are taken up for this study attending Out patient department at Rangaraya Medical College, Kakinada, AP, India. Out of which 80 cases are included for this study remaining are excluded as per criteria. Results: Commonest age group involved in this study was 41-50 followed by 31-40. Males are most commonly affected (87.5%).Most commonly Laburers are commonly affected about 75%. Cough (100%) followed by Expectoration, Haemoptysis and fever are the most common symptoms. Most common finding in respiratory examination was crepitations about 75%. And this alone present about 40% of patients. Wheezes were seen in 25% and bronchial breath sounds were seen in 37.5% of patients. Renal function test are normal for almost all patients. Most common finding in Chest X ray was infiltrations about 93%, total percent of cavitation was 38% and total percent of pleural effusion was 9%. And infiltration are most commonly seen in upper zone about 81.25% followed by mid zone involved about 55% and lower zone was 12.5%. Only 2.5% of patients sputum sample wee showing resistance to Rifampicin out of 80 patients. Conclusion: RIF resistance is the main indictor of MDR TB because the resistance to RIF mostly combined with the resistance for Isoniazid. Since, this is the indicator for prevalence of MDR-TB and all new smear positive patients should be screened for the same to early detection, prevention of spread and management of MDR-TB.

Keywords: Tuberculosis, Rifampicin, Pleural effusion, MDR-TB, Haemoptysis, Cough.

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#### Introduction

Tuberculosis (TB) is an infectious disease which spread by Mycobacterium tuberculosis. TB primarily usually infect the lungs which is called as Pulmonary TB (PTB). Tuberculosis is one of the main diseases of low socioeconomic status along with HIV. A one third of world's peoples is found to be affected by M. Tuberculosis, its infects others by rate of one per second. It is the infection of poor mostly on the young adults[1].

Drug resistance TB is the burden of illness in the society with several constraints in the management of TB patients. Using of Highly effective regimens utilizing the drugs that have not been prescribed previously and known to posses good anti mycobacterium activity needs to be implemented , which increases operational expenses in drugs and its distribution, monitoring the toxicity of the drugs and supervision of the administration of drugs to ensure the intake regularly. Though the efficacy of the drugs in the management of pulmonary tuberculosis is well established , and its application on a mass level under the home based treatment programme gives much worries due to operational difficulties. With the poor drug compliance of patients causing markedly increases in number of patients having drug resistant TB bacilli in the community[2,3].

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Tuberculosis is the disease treatable with a full course of Anti TB drugs. Multi Drug Resistance Tuberculosis (MDR-TB) is described as the resistance to anyone of the first-line TB drugs Rifampicin and Isoniazid. The Extensively drug-resistant TB (XDR-TB) is called because of resistant of drugs to the 3 or more than three of the 6 types of second-line drugs. This is a matter of global concern.

#### Aims

This study mainly focuses on the detection, comparison of prevalence of MDR-TB among New smear sputum Positive TB patients. And To determine thepattern of drug resistance in them.

## Objectives

- To determine the prevalence of Drug resistance in New smear sputum positive patients during study period.
- To determine the drug resistance to Rifampicin among them by using Cartridge Based Nucleic Acid Amplification Test (CB-NAAT) [GeneXpert].
- To analyze the drug resistance of New smear sputum positive Patients to decidewhether the DOTS PLUS regimen should start early

## Methodology

- The study is will be undertaken on the patients attending medicine outpatient department and admitted in the RangarayaMedical College and Hospital, Kakinada during the study period (July 2018 to June 2019). A total of 80 patients of new smear positive pulmonary tuberculosis will be included in the study.
- The list of the patients enrolled in the study is appended along with the dissertation. The study excludes minors, pregnant women, mentally-ill and non-volunteering patients, Presence

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of secondary immunodeficiency states- HIV, Diabetes, cancer patients, patients on corticosteroids or cytotoxic drugs, Extra pulmonary TB, Pregnancy and lactation, Hepatitis B or C

ections.

The study is proposed to be conducted after obtaining informed signed consent from the patients. The duration of the study is one year from July 2018 to June 2019. The principal investigator, after obtaining informed signed consent from the patients to participate in the study, collects their baseline characteristic details, medical history details and physical examination details.

- The clinical history includes all risk factors like close contact with known MDR-TB or with person who died of TB/ failed treatment, failure to improve on current TB treatment and association with HIV or other immuno suppressions.
- Diagnosis of TB will be confirmed as per Revised National TuberculosisControl Programme (RNTCP) guidelines.
- Sputum or gastric lavage of all cases will be sent for Culture and Drug susceptibility test (DST).
- DST will be done by detection of drug resistant gene for

Rifampicin by Cartridge Based Nucleic Acid Amplification Test (CB-NAAT) [GeneXpert] at the Culture and Drug Susceptibility Testing Laboratory, Department of Thoracic Medicine, Coimbatore Medical College Hospital. Coimbatore.

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#### Investigations

- 1. Complete Haemogram
- ESR
- 3. RBS, B.Urea, S.creatinine
- 4. Liver function Test
- Urine Complete
- 6. Chest X Ray
- 7. HIV Test 1&2
- 8. CB-NAAT (Gene Xpert)

## Results and observations

Table 1: Distribution of age

AGE in yrs	Frequency	Percent
<10	1	1.25
11 to 20	4	5
21-30	15	18.75
31-40	18	22.5
41-50	20	25.0
51-60	12	15
61-70	08	10
>70	02	2.5
Total	80	100.0

Table 2: Distribution of sex

SEX	Frequency	Percentage
Female	10	12.5
Male	70	87.5
Total	80	100.0

Table 3: Distribution of occupation

Occupation	Frequency	Percentage
DRIVER	12	15
HOME	4	5
MAKER		
LABOURER	60	75
STUDENT	04	5
Total	80	100.0

- 1. Total number of patients studied were .80
- 2. Out of 70 patients Male patients were 10 and female patients were 16 innumbers.
- 3. Most number of patients were in the age group 41-50 followed by 31-40.4. Total number of patients in the age group 41-50 were 20 (25%)

4. 75% of patients were Laborers, 15% of patients are drivers, 5% of patientswere students and 5% were Home makers

Table 4:Distribution of cough
Cough Frequency Percentage

Table 5:Distribution of cough expectoration

Cough with Expectoration	Frequency	Percent
NO	5	6.25
YES	75	9375
Total	80	100.0

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Table 6:Distribution of haemoptysis

Haemoptysis	Frequency	Percentage
NO	55	68.75
YES	25	31.25
Total	80	100.0

Table 7: Distribution of fever

Fever	Frequency	Percentage
NO	50	62.5
YES	30	37.5
Total	80	100.0

- 1. All patients were having Cough(100%)
- 2. 93.75% of the patients were having Cough with Expectoration
- 3. 31.25% of the patients were having Haemoptysis
- 4. 37.5% of the patients were having fever
- 5. Most Common symptom with which patients were presented with Cough(100%) followed by expectoration (93.75%).

Table 8: Distribution of pallor in general examination

Pallor	Frequency	Percent
NO	25	31.25
YES	55	68.75
Total	80	100.0

Table 9:Distribution of the poor nutrition

<b>Poor Nutrition</b>	Frequency	Percent
NO	70	87.5
YES	10	12.5
Total	80	100.0

Table 10:Distribution of crepitations (respiratory finding)

Crepitations	Frequency	Percent
NO	20	25
YES	60	75
Total	80	100.0

Table 11:Distribution of wheeze

Wheeze	Frequency	Percent
NO	60	75.0
YES	20	25.0
Total	80	100.0

Table 12: Distribution of bronchial breath sounds

<b>Bronchial Breath Sounds</b>	Frequency	Percent
NO	50	62.5
YES	30	37.5
Total	80	100.0

- 1. 68.75% patients were looking pallor in General examination
- 2. 12.5% patients were with Poor nutrition in General examination
- 3. 75% patients were presented with crepitations
- 4. 25% patients were presented with wheeze
- 5. 37.5 % patients were presented with Bronchial breath sounds
- 6. Most common sign presented in examination were crepitations followed bybronchial breath sounds

Table 13: Distribution of anaemia

Anaemia	Frequency	Percent
NO	20	25.0
YES	60	75.0
Total	80	100.0

Table 14: Distribution of sputum a sample

Sputum A	Frequency	Percent
0	6	7.5
1+	35	43.75
2+	17	21.25
3+	12	15
SO2	5	6.25
SO4	1	1.25
SO5	3	3.75
SO6	1	1.25

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Total	80	100
Total	80	100

Table 15:Distribution of sputum b sample

Sputum B	Frequency	Percent
0	1	1.25
1+	46	57.5
2+	15	18.75
3+	16	20
SO3	1	1.25
SO6	1	1.25
Total	80	100.0

- 1. 75% of patients were anaemic.
- 2. In sample A, sputum for AFB 43.75% patients were having 1+, followed by 21.5%, 15% for 2+ and 3+ viz.
- 3. In sample B, sputum for AFB 57.5% patients were having 1+, followed by 18.75%, 20% for 2+ and 3+ viz.
- 4. All 80 patients are positive for AFB stain.

Table 16: Distribution of upper zone infiltration in chest xray

<b>Upper Zone Involvement</b>	Frequency	Percent
NO	15	18.75
YES	65	81.25
Total	80	100.0

Table 17: Distribution of mid zone infiltration in chest xray

Mid Zone	Frequency	Percent
NO	36	45.0
YES	44	55
Total	110	100.0

Table 18: Distribution of lower zone infiltration in chest xray

Lower Zone	Frequency	Percent
NO	70	87.5
YES	10	12.5
Total	80	100.0

Table 19: Distribution of rifampicin resistance

RIF Resistance	Frequency	Percent
NO	78	97.5
YES	2	2.5
Total	80	100.0

- 1. A total number of 65 patients, 81.25% were having Upper zone infiltration in Chest Xray.
- 2. With total number of 44 patients 55 were having Mid zone infiltration withupper zone in Chest Xray.
- 3. In10 patients,12.5% were having lower zone infiltration in Chest Xray.
- 4. Most commonly presented with upper zone consolidation or fibro cavity
- 5. Only 2.5% of patients are having Rifampicin Resistance have been identified by GeneXpert done for all 80 patients.

#### Discussion

This study was conducted in Coimbatore medical college hospital from July 2018 to July 2019. This is a cross sectional type of study. In this study total number of 100 patients were taken and 80 patients were studied. 20 patients were excluded based on the exclusion criteria. The clinical and diagnostic findings of this study are compared with our studies in literature here.

Out of 80 patients, 84 patients were male and remaining 16 were female. Majority of patients were in the age group of 41-50 (25%) followed by 31-40(23%). And about 69% of patients were labourers and followed by drivers. There were 35% of smokers.

Most common symptom was cough (100%), followed by Cough with expectoration (93.75%), haemoptysis (31.25%) and fever (37.5%).

Most common finding in general examination were pallor (68.75%) followed by poor nutrition(12.5%).

In auscultatory findings were seen Crepitations (75%), Bronchial breath sounds (37.5%) and wheeze(25%) in viz. And in laboratory findings anaemia seen in nearly 75% of patients.

In Chest xray findings most commonly infiltrations seen in upper zone followed by middle and lower zones.

The comparison of the above shows almost equal in symptoms except

for fever which is high in bikaram Singh study[4]. Likewise 100% cough seen inour present study.

Since the drug resistance in tuberculosis are increasing in trend globally, early detection of MDR-TB is essential.

In this study, only 2 patients were having Rifampicin resistance seen inout of 80 patients detected by using the GeneXpert.

Drug Resistance surveillance (DRS) were conducted at many of the states in our country such as Maharastra, Gujarat and Andhra Pradhesh and its results gives as the prevalence of MDR TB was about 2-3% in new cases and nearly 17% in old cases.

The drug resistance TB – surveillance and resistance report 2014 of WHO shows about 3.5% cases were MDR-TB in the globe.

Another study Sharma Et Al Prevalence Of MDR-TB in New Pulmonary Tuberculosis Cases estimated about 1.1 % for Rifampicin resistance[5].

And Lukoye D et al[6] did the study on drug resistance new and previously treated sputum smear-positive tuberculosis patients in Uganda shows the Rifampicin resistance about 1.9%.

## Conclusion

1. In this study most common manifestations of New sputum

pulmonary tuberculosis were cough with expectoration followed by fever, weight loss, haemoptysis. Most commonly upper zone

decreased haemoglobin, white blood cells and increases ESR. Possibility of drug resistance is seen new smear positive pulmonary tuberculosis.

of the lungs were involved. Most of the patients showed

- Resistance to Rifampicin were found in new sputum positive TB patients by using GeneXpert.
- Prevalence of Drug resistance to Rifampicin in our locality is about 2.5%. to compare with national and international prevalence it was low.
- Multi Drug Resistance Tuberculosis (MDR-TB) is described as the resistance to anyone of the first-line TB drugs Rifampicin and Isoniazid
- RIF resistance is the main indictor of MDR TB because the resistance to RIF mostly combined with the resistance for Isoniazid.
- Since, this is the indicator for prevalence of MDR-TB and all new smear positive patients should be screened for the same to early detection, prevention of spread and management of MDR-

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