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Drug Utilisation Study for Pulmonary Tuberculosis Patients in a Tertiary Care Teaching Hospital

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Abstract

Tuberculosis or TB, is a contagious infection that usually affects the lungs. In this prospective observational study, patients in latent stage prescribed with medications who are eligible were enrolled after obtaining consent. A data collection form was prepared and used which broadly covers the demographic details of patient and prescribed medication. Information relevant to study was collected from time of admission till discharge and the data was analyzed using respective methods for statistical analysis. From the data thus obtained it was observed that Early stage Patients were responding better to 3-drug regimen therapy when compared to severe stage patients response to 4-drug regimen therapy. Up on further study it is concluded that TB possibility is high in males with age of 21-40 years and risk increases with social behaviour of the patient, rural population are more prone than others along with patient compliance to treatment and preventive measures.

Key words: Tuberculosis, Drug regimen therapy, Staining, Treatment outcomes.

1. INTRODUCTION

Tuberculosis (TB) is associate communicable disease that typically affects the lungs, although it will have an effect on any organ within the body. It will develop once microorganism unfolds through droplets within the air. TB will be fatal, however in several cases, it's preventable and treatable. TB is caused by a kind of bacteria referred to as Mycobacterium tuberculosis. Other pathogens include *M. bovis*, *M. avium*, *M. africanum*. Robert Koch, in the year 1882 discovered and reported the bacteria *Mycobacterium tuberculosis*[1]. Spread occurs through air if someone with active TB condition coughs or sneezes and the expelled droplets are inhaled by someone around. Once someone gets active TB sickness, it suggests that, the *mycobacterium* is multiplying in the lungs and/or also other parts of the body such as lymph nodes, bones, kidney brain, spine and even the skin. From primary site of infection i.e. lungs TB bacteria transfuse into the circulatory system and spreads to other body parts including kidneys, spine or brain. In cases of extra-pulmonary TB, signs and symptoms vary

according to the involved organs. For example, in Tuberculosis of Spine, symptoms such as severe back pain and in Renal Tuberculosis, blood in the urine (Hematuria) can be seen.

In the 1980s, number of TB patients started to rise again and as a result World Health Organization (WHO) described it as an "epidemic".WHO reported TB among the top 10 causes of death globally and "the leading cause of death from a single infectious agent." According to estimations of WHO, in the year 2018, nearly 10 million people around the world developed and active TB and 1.5 million people died from the disease, including 251,000 people who also had an HIV infection. The major population according to this report, belongs to Asia.[2]

1.1 Types of TB:[3,4]

1. Primary Pulmonary TB.
2. Secondary TB (miliary, fibrocaseous, cavitary).
3. Extra Pulmonary TB (bones, joints, renal, adrenal, skin).

1.2 Signs and symptoms of active TB include:[5]

Chronic cough which lasts for three weeks or more, coughing blood, severe chest pain, or pain while breathing or coughin, uncontrolled weight loss due to loss of appetite, fever, tiredness, chills, night sweats.

1.3 Risk factors:[6,7]

Malnutrition, HIV/AIDS, Diabetes and other immune-compromised conditions, chemotherapy for cancer, use of drugs for graft rejection, Psoriasis, Rheumatoid arthritis, Crohn's Disease very young or old age.

The major treatment recommendations include the following four TB drugs (4-drug regimen therapy) Isoniazid (INH) 10mg/kg (range 10-15 mg/kg); maximum dose 300 mg/day, Rifampicin (R) 15mg/kg (range 10-20 mg/kg); maximum dose 600 mg/day, Pyrazinamide (Z) 35mg/kg (30-40) mg/kg) Ethambutol (E) 20mg/kg (15-25 mg/kg). The 3-drug regimen therapy excluded Pyrazinamide drug[8].

2. MATERIALS AND METHODS:

This was an observational type of study done in the outpatient and inpatient department of pulmonary department of a tertiary care hospital in Mahabubnagar, Telangana. Ethical permission from institution ethics committee was obtained. SVSMC/IEC/IEC Approval No. 006-2019. The sample size was 100. The study duration was 1 year, in which TB patients of 18 years and above was selected for participation in this study. After obtaining informed consent, history was recorded. Patients who have MDR TB and Extra Pulmonary TB cases are excluded.

2.1Methods of Diagnosis:[9,10,11]

2.1.1For Positive Sputum Test:

The sputum is taken early morning, which is thick and purulent (broncho-sputum), before the patient has taken any food, in a wide-mouthed, sterile disposable containers, and centrifuged at 3000rpm per minute for 30-minutes with addition of 5% NaOH solution, such that the sputum is isolated from other debris, cells likes neutrophils, saliva, food content, etc. the supernatant liquid is discarded into another tube. The leftover sample in tube contains only sputum or expectorant.

Now the sputum is taken for homogenisation with addition of 5ml 1% HCl (to neutralise NaOH), where the thick sputum collected after decontamination is made into fine pourable liquid. This method is performed to remove any air bubbles left after decontamination and reduction of viscosity of sputum.

2.1.1.1 When sputum is taken as smear:

Sputum is taken on microscopic slides and gently heated for 5minutes on mild flame after which the degeneration of mycolic acids in membrane of bacteria occurs. The slide is Stained with Carbol-fuschin dye and decolorised with 5% Sulphuric acid or 5% Hydrochloric acid.Wash with distilled water, let it dry then Zein-Neilson stain is added to smear followed with Methylene blue indicator. Oil immersion is added to remove air bubbles then observed under microscopic lens (100x).

2.1.1.2 When the sputum is taken on culture medium:

The sputum is added to Lowenstein Jensen (LJ) medium that is incubated at 37^0C for 2-6 weeks. A creamy or yellowish coloured growth of bacteria. To this the straining techniques are performed. Oil immersion is added to remove air bubbles and then observed under microscopic lens (100x).

Observation: Rod shaped, pink coloured, slender, slightly curved beads are appeared. The colour gradient increases based on severity of bacterial contamination.

2.1.2 For Negative Sputum Test:[12]

Chest X-ray is taken to check the presence of consolidations in Lungs, made of *Mycobacterium tuberculi*.

Technique : Automated X-ray scanner

View : Posterio-Lateral/ Posterio-anterior

Exposure : 66KV 20mAS

Device : ALLENS – 500 / SIEMENS – 300 /ALLENGES - 625

Manufacturer : Allens medical systems private limited

Reader : Fujifilm FCR Primac

3. RESULTS:

Age wise distribution shows that TB is more prevalent in 21-30 years, 51-60 years and 61-70 years age group and less prevalent in other age groups. It also observed that male are prevalent to TB than female.

Table 1 "Age and Gender wise" distribution of sample population in the study:

Characteristic	Male	Female	Total
Age Group (in years)			
1-10	00	01	01
11-20	00	05	05
21-30	16	06	22
31-40	08	06	14
41-50	07	02	09
51-60	16	07	23
61-70	17	04	21
71-80	01	01	02
81-90	02	01	03
Total	67	33	100

Table 2: Classification based on Comorbidity

Comorbid conditions	No. of cases	Percentage
Hypertension	15	18.98
Diabetes	25	31.64
Pleural effusion	20	25.31
Under nutrition	6	7.59
Asthma	1	1.26
Seizure	1	1.26
Cirrhosis	1	1.26
COPD	1	1.26
cardio vascular arrest	1	1.26
Hypothyroidism	1	1.26
Ascities	2	2.53
Pneumothorax	2	2.53
Hepatitis	1	1.26
Osteomyelitis	1	1.26
Meningitis	5	6.32

On assessing the prevalence of comorbidities, 31.64% (25) of TB patients in the study were found to be Diabetic, 25.31% (20) were found to be having Pleural Effusion and 18.98 % (15) were found to be Hypertensive. Other comorbidities such as Seizure, Cirrhosis, COPD, Ascites, Hepatitis were less prevalent.

Table 3: Frequency distribution based on habit

S. No	Social habit	No. of patients
1	Alcoholic	10
2	Tobacco consumers	26
3	Alcoholic + tobacco consumer	27

On assessing the social habits of the patients, 27 patients were alcoholic and tobacco consumers, 26 were only tobacco consumers, and 10 patients were alcoholic.

Table 4: Frequency distribution based on their Locality

S. No	Locality	No. Of patients
1	Rural	68
2	Urban	32

68 patients belonged to Rural locality whereas only 32 patients were from urban locality.

Table 5: Frequency Distribution based on sputum culture

Sputum Culture	Positive	Percentage	Negative	Percentage
Male	60	69.76%	10	71.42%
Female	26	30.24%	4	28.58%
Total	86		14	

On analyzing the Sputum culture reports, 86 TB patients showed positive and 14 patients showed negative reports.

Table 6: Frequency distribution based on chest X- ray examination

Chest X-ray performed in month	No. of Patients
Initial phase	100
Continuous phase (3rd month)	56
Continuous phase (6th month)	39

Table 7: Frequency of distribution based on sputum culture performed during 3rdmonth and 6thmonth.

Sputum culture performed in month	No of patients
Initial phase	100
Continuous phase (3rd month)	40
Continuous phase (6th month)	24
Continuous phase (3rd& 6th month)	15

FIGURES:

Fig-1& 2: Examining in Hospital:

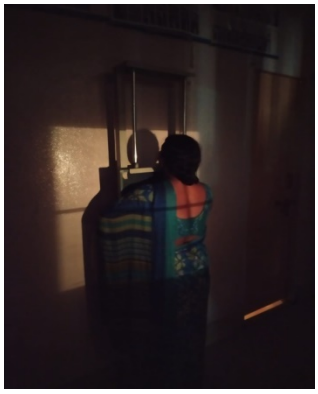
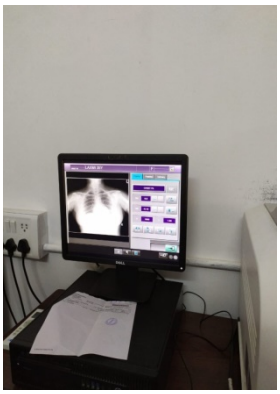


Fig-3 & 4 : chest X ray examination:



Chest X-Ray was performed at initial phase, 3rd month and 6th month continuous phase for the patients. In the 3rd month chest X-Ray was taken of 56 patients and by the end of 6th month, only for 39 patients' chest X-Ray was performed.

Table-8: Distribution based on their combination of drugs prescribed in accordance with treatment outcomes.

Treatment outcomes	4-drug combination	3-drug combination	Total
Cured	23	18	41
Completed	14	14	28
Loss of follow up	18	00	18
Failed	05	05	10
Died	03	00	03
Successful treatment(cured + completed)	37	32	69
Poor treatment(lost of follow up + failed + died)	26	05	31

In the prescribed 4-drug combination and 3-drug combination regimens, 37 patients with 4-drug regimen and 32 patients with 3-drug regimen showed successful results and were cured completely. Similarly, 26 patients with 4-drug regimen and 5 patients with 3-drug regimen showed unsuccessful results (due to loss of follow-up or failed treatment) and among these 31 poor treatment individual, 3 deaths were reported during the treatment.

4.DISCUSSION:

When age wise distribution of 100 PTB patients were analyzed, maximum number of cases were found to be between age group of 51-60 years (23) with 23.0% of patients and minimum number of cases was in the age group 01-10 years (01) with 01.00% of patients. After excluding the death and lost o9f follow up cases total no. of patients are found to be 79 among them it was studied that maximum number of cases were found to be between age group of 21-30 years (22) with 27.84% of patients and minimum number of cases were in the age group 01-10, 71-80, 81-90 years (01) with 1.26% of total patients. Gender wise distribution, maximum numbers of Patients were Male 67 (67.0%) and followed by female 33(33.0%).

Frequency Distribution based on sputum culture results were found as 86 samples as positive and 14 were negative. Frequency distribution based on comorbid conditions, and it was found that many cases had reported comorbidities like diabetes 25 (31.64%), plural effusion 20(25.31%), Hypertension 15(18.98%), under nutrition 6(7.59%), meningitis 5(6.32%), Pneumothorax and Ascities 2 (2.53%), and hypothyroidism, asthma, seizure, cirrhosis, COPD, CVA and hepatitis 1(1.26%) each.

Frequency distribution based on combination of drugs prescribed in accordance with treatment outcomes were observed and among them, 37 severe stage TB patients using 4 drug combination attained their successful treatment whereas 26 patients have shown poor outcomes. In 3-drug combination, 32 early stage TB patients had shown successful treatment and 05 patients have shown poor treatment outcomes.

CONCLUSION

After the study it is concluded that Early stage TB patients were well responded to 3-drug regimen therapy compared to severe stage TB patients were treated 4-drug regimen therapy and also possibility is high in male gender and with age group of 21-40 years and the risk factor increases with the social behaviour of the patient consuming alcohol and tobacco. Mainly rural population was more exposed to TB. The diagnosis was done based on the sputum staining techniques and chest X-Ray and data were collected. Upon giving various drug combinations the success and poor treatment out comes were observed accordingly. The poor treatment out comes has aroused due to poor patient compliance to the treatment and preventive measures.

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