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Research Article

A PROSPECTIVE OBSERVATIONAL STUDY ON THE OUTCOME OF TUBERCULOSIS TREATMENT IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Tuberculosis (TB) remains one of the deadliest infectious diseases responsible for millions of deaths annually across the world. In developing countries the incidence of tuberculosis has been increasing steadily, the most serious infectious causes of all the global mortality and morbidity. The principle aim is to assess the prescribed Tuberculosis treatment and curative outcome of patients registered for Tuberculosis treatment. A Prospective Observational study was conducted in Tuberculosis Unit of Pulmonology Department, Sri Venkateswara Ramnarain Ruia Government General Hospital, a tertiary care hospital in Tirupathi, Andhra Pradesh, India for 6 months duration with a sample size of 150. In this study male were predominant with 87 (58%), age group of 41-60 years were predominant. Pulmonary Tuberculosis cases were 136 and Extra Pulmonary Tuberculosis was 14; the patients with Diabetes Mellitus (45%), HIV (24%), Alcohol (28%) and Smoking (40%). The cases under category I and II were 100 and 50; the sputum positive, sputum negative and sputum not done were 127, 14 and 9 respectively. The sputum score was 1 in 16, 2 in 53, and 3 in 58. Treatment success rate was 81%, treatment failure was 3%, defaulter, transferred out and mortality rate were found to be 6%, 4% and 6% respectively. Despite of success rate we still observe considerable rate of treatment failure due to resistance, non-compliance totreatment and lack of awareness in the patients about importance of Tuberculosis treatment. Further efforts should be made by responsible bodies to include clinical pharmacists to improve success rate of Tuberculosis treatment, as clinical pharmacist play a key role in educating the patients.

Keywords: Tuberculosis, Treatment outcome, Curative rate

INTRODUCTION

Tuberculosis (TB) is air born droplet disease caused by *Mycobacterium tuberculii* that most often affect the lungs (Pulmonary tuberculosis), it is curable and preventable. A person suffering with Pulmonary Tuberculosis coughs sneezes, spits then they release the bacteria (*Mycobacterium*) into air, other person who inhales them gets infected and become affected. Tuberculosis is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS)[1] worldwide. Tuberculosis is one of the dangerous and deadliest infectious diseases responsible for millions of deaths across the world, causing the global mortality and morbidity. It causes a great deal of ill health and enormous burden on population of most low and middle income countries[2].

From the world census one-quarter has latent Tuberculosis, which means people have been infected by *Mycobacterium tuberculii* but are not (yet) ill with the disease and cannot transmit the disease. Every person who is latent doesn't comprise of affecting with TB but they are at a risk of getting infection with the *Mycobacterium tuberculii* i.e., these people have a 5–15% lifetime risk of getting ill with tuberculosis. The persons with compromised immune systems such as people living with HIV, malnutrition or diabetes or people who use tobacco, have a much higher risk of getting easily attacked with disease and falling ill[2].

In 2017, Tuberculosis was estimated, 1.3 million deaths (range, 1.2–1.4 million) among HIV-negative people and an additional 300,000 deaths from Tuberculosis (range, 266,000 – 335,000) among HIV-positive people. Globally, the best estimate is that 10.0 million people (range, 9.0–11.1 million) developed Tuberculosis in 2017: 5.8 million men, 3.2 million women and 1.0 million children[1,3].

In 2017, the largest number of new Tuberculosis cases occurred in the South-East Asia and Western Pacific regions, with 62% of new cases, followed by the African region, with 25% of new cases, 87% of new Tuberculosis cases occurred in the 30 high Tuberculosis burden countries. Eight countries accounted for two thirds of the new Tuberculosis cases India, China, Indonesia, the Philippines, Pakistan, Nigeria, Bangladesh and South Africa[2].

Tuberculosis in India

As per the Global Tuberculosis report 2017 the estimated incidence in India was approximately 28, 00,000 accounting for about a quarter of the world's tuberculosis cases. In Andhra Pradesh, India out of 5.15 crore population, 83118 cases were noticed (67074 cases were notified from public sector and 1604 cases were notified from private sector). In Chittoor out of 43 lakh population, 6295 cases were identified (4499 cases from public sector and 1796 cases from private)[4].

Table 1: Tuberculosis treatment outcomes

Outcome	Definition
Cure	A person who is positive for the culture or smear, then initiates treatment and shows negative in the end of the treatment or during the treatment
Treatment completed	A patient who completed the treatment but doesn't have any reports showing the negative for culture or smear in the end of treatment course or any previous occasion.
Treatment failure	A patient obtaining positive results for either sputum or culture even on taking the treatment in the last days of treatment course or after the end of treatment.
Died	Death of the patient during the course of treatment with any reason.
Default	Interruption in the treatment uptake by the patient for 2 or more months
Transferred out	A patient transferred to another region and treatment outcome is not known.
Treatment success	Cure and Treatment completed

MATERIALS AND METHODS

A Prospective Observational Study was conducted in Tuberculosis Unit of Pulmonology Department, Sri Venkateswara Ramnarain Ruia Government General Hospital and A 1200 bedded tertiary care hospital in Tirupati, Andhra Pradesh, India. The study was carried out for a period of six months (July 2018 to December 2018) with a sample size of 150 patients. Ethical approval: SPSP/2018-2019/PD01

Inclusion criteria

- Patients visiting TBCD Ward and RNTCP for receiving treatment for tuberculosis.
- The patients receiving Anti Tubercular Therapy irrespective of their co-morbidities and are willing to participate in the study.

Exclusion criteria

- Patients who are not willing to participate in the study.
- Patients who are below 20 kg body weight.
- Patients of age group less than 12 years.
- Patients visiting other than Pulmonology department.
- Patients with MDR-TB and XDR –TB.

Patient's data collection proforma, Informed consent form (ICF), Treatment charts, WHO Tuberculosis Guidelines 2014, 2017 (revised), RNTCP Programme of India (2012-2017) were used as the study materials in the study.

A specially designed proforma was used for collecting data which includes patient demographics, past medical history, personal habits, co-morbities, diagnosis and present medication prescribed for each patient. The data was obtained from patient by patient / patient care taker visited to the RNTCP for direct treatment (tablets refilling), interview was done and also from patient case profiles. All the 6 months treatment was analyzed for the appropriate curative outcome, changes in patient's body weight, drug related problems. Based on the severity and the nature of drug related problems they were brought to the notice of concerned physician or other health care professional by clinical pharmacist to take necessary action. During the interview the patient is provided with the awareness on Tuberculosis to minimize the morbidity of disease spread in the society and also to improve the health related quality of life (HRQoL) of patient.

Statistics

Microsoft office, Excel 2016 was used to produce the results in the form of charts and percentages.

RESULTS

Table 2: Baseline demographic details of the tubercular patients (n = 150)

Patient characters	PTB	EPTB	No. of patients (n)	Percentage (%)
Gender wise distribution				
Female	54	9	63	42
Male	82	5	87	58
Age wise (in years) distribution				
13 – 20	5	3	8	5
21 – 30	16	2	18	12
31 – 40	30	4	34	23
41 – 50	38	0	38	25
51 – 60	34	4	38	25
> 60	13	1	14	10
Body weight on initiation (in kgs)				
< 40	14	1	15	10
41 – 50	49	3	52	34
51 – 60	50	8	58	39
> 60	23	2	25	17
Social Habits				
Smoker	12	0	12	8
Alcohol	30	0	30	20
Smoker and Alcohol	26	2	28	19
No smoking and No Alcohol	68	12	80	53
Risk Factors				
HIV	21	3	24	
T_2DM	41	4	45	

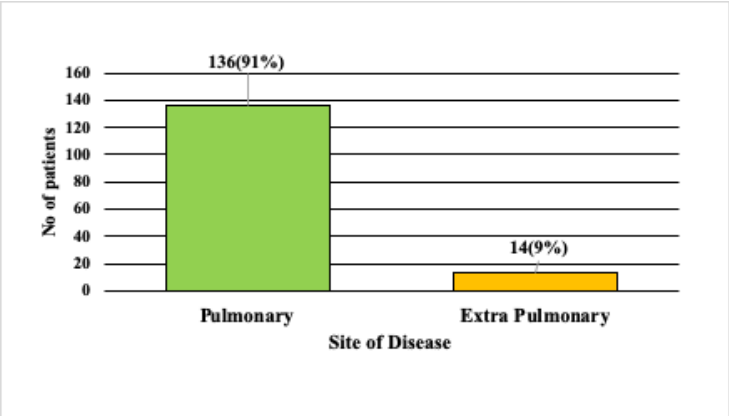


Figure 1: Type of Tuberculosis

Table 3: List of patient types and treatment categories

Parameters	PTB	EPTB	No. of pts (n)	Percentage (%)
Types of patients under TB treatment				
New	90	10	100	67
Recurrent	23	2	25	17
Non follow up	15	0	15	10
Others	8	2	10	6
Category of treatment				
Category – I	90	10	100	67
Category – II	46	4	50	33

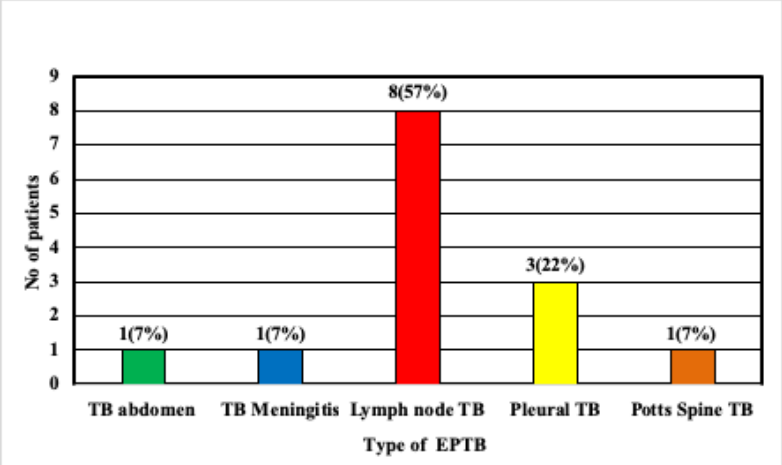


Figure 2: Classification of Extra pulmonary tuberculosis

Table 4: Diagnostic parameter

Parameters	PTB	EPTB	No. of pts (n)	Percentage (%)
Confirmative test for TB through sputum analysis				
Sputum +ve	127	0	127	85
Sputum –ve	6	8	14	9
Test not done	3	6	9	6
Severity of TB (Sputum score)				
+1	16	0	n =127	-
+2	53	0		
+3	58	0		

Table 5: Distribution of patients based on monthly monitoring of body weight

S. No.	Body weight (kg)	No. of patients (Month wise)						
		0th	1st	2nd	3rd	4th	5th	6th
1.	20-25	1	1	1	1	0	0	0
2.	26-39	8	6	7	4	5	4	4
3.	40-54	72	85	78	71	66	62	60
4.	55-69	63	50	51	51	50	53	54
5.	≥ 70	6	6	6	6	6	7	8

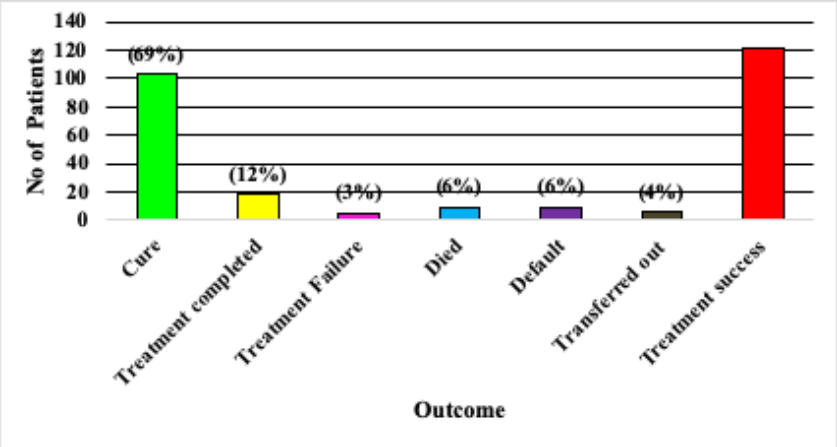


Figure 3: Classification of treatment outcome

DISCUSSION

Tuberculosis remains one of the deadliest infectious diseases responsible for millions of deaths annually across the world. It is the most serious infectious causes of all global mortality and morbidity. It causes a great deal of ill health and enormous burden on population of most low and middle income countries. People infected with tuberculosis bacteria have a 5–15% lifetime risk of falling ill with tuberculosis. However, persons with compromised immune systems, such as people living with HIV, malnutrition or diabetes or people who use tobacco, have a much higher risk of falling ill.

In the present study, 150 subjects were analysed for the tuberculosis treatment patterns and their curative outcome. The study showed that majority of people diseased were belonged to 41-60 year age group[5]

The study indicates, the males were dominant[6,7] with 58% On initiation of therapy patient's body weight were found to be < 40 kg were 15 (10%) patients, followed by 41-50 kg were 52 (34%) patients, 51-60 kg were 58 (39%) and > 60 kg were 25 (17%). The majority of the patients belong to 51-60 kg body weight[8].

The major risk factors for tuberculosis were HIV (AIDS), Diabetes Mellitus (type 2), Smoking, and Alcohol.

In the study, 30 (20%) patients were alcoholic followed by 12 (8%) patients were smokers, 28 (19%) were both alcoholic and smokers and 80 (53%) patients were Nil (alcoholic and smoking) i.e., without any social habits respectively[9].

HIV co-infection exacerbates the severity of tuberculosis disease while additionally tuberculosis co-infection accelerates HIV replication in affected organs including lungs and pleura while DM shows three folds increased risk of tuberculosis compared to the nondiabetic.

Alcohol has been recognized as the increased risk factor for tuberculosis, the reasons for increased risk includes alteration in the immune system, specifically in altering the signalling molecules responsible for the cytokine production. Association between Smoking and tuberculosis is impaired clearance of mucosal secretion, reduced phagocytic ability of alveolar macrophages and decrease in the immune response and/or CD^{4+} lymphopenia due to the nicotine in the cigarettes have been given as reasons for increased susceptibility to pulmonary tuberculosis.

From the study it was revealed that most of the cases shown positive response to the sputum tests and the positive response obtained were maximum presented with sputum score 2 and 3[10].

Majority of the cases were obtained were pulmonary tuberculosis which would be due to the risk factors, lowered immune response etc.[11]

On overall assessment of the study new cases were found to be major who indicates the increasing morbidity[12]. Out of 14 extra pulmonary cases, there were different systems involved, leading to different types of diseases, with 1 (7%) case belongs to tuberculosis abdomen, 3 (22%) cases belong to tuberculosis Pleura, 8 (57%) cases belong to tuberculosis of Lymphnode, 1 (7%) case belongs to tuberculosis Meningitis and 1 (7%) case belongs to Potts Spine tuberculosis respectively[13].

The treatment regimens preferred were based on the type of tuberculosis with 2 different treatment categories. 100 (67%) cases were given treatment under Category-I and 50 (33%) cases were treated according to Category-II respectively.

81% (121) of treatment success was obtained from this study and the other outcomes were Cure were 103 (69%) cases, Treatment completed were 18 (12%) cases followed by Treatment failure were 5 (3%) cases, died were 9 (6%) cases, default were 9 (6%) cases, transferred out were 6 (4%) cases respectively[14]

CONCLUSION

The study revealed that even though there is high success rate in present by following Tuberculosis treatment guidelines still we observe considerable rate of treatment failure this is because of non-compliance, resistance to treatment and lack of awareness in the patients about importance of Tuberculosis treatment. So, our study suggests further efforts should be made by responsible bodies to include clinical pharmacists to improve success rate of Tuberculosis treatment. As clinical pharmacist play a key role in educating the patients, our study intensifies the role of clinical pharmacist in improving the awareness in the patients about the Tuberculosis treatment and also to increase the treatment success rate.

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