



ORIGINAL RESEARCH PAPER

Medicine

TREATMENT OUTCOME OF DOTS REGIME IN TUBERCULOSIS PATIENTS IN TERTIARY CARE CENTRE

KEY WORDS:

Dr. Supinder Singh*	Resident Medicine, Acharya Shri Chander College of Medical Sciences and Hospital, Jammu and Kashmir. *Corresponding Author
Dr. Puneeta Gupta	Professor of Medicine, Acharya Shri Chander College of Medical Sciences and Hospital Jammu and Kashmir.
Dr. Amardeep Kour	Consultant, ICDS Department, Jammu and Kashmir.
Dr. Zahoor Ahmad Zahoor	Resident Medicine, Acharya Shri Chander College of Medical Sciences, Jammu and Kashmir.
Dr. Haji Jawaid-ul Hassan	Resident Medicine, Acharya Shri Chander College of Medical Sciences and Hospital, Jammu and Kashmir.
Dr. Rajat Bral	Consultant Resident Medicine, Acharya Shri Chander College of Medical Sciences and Hospital, Jammu and Kashmir.

Introduction

Tuberculosis is a common infectious disease known to humanity since ages. It is highly prevalent in India and other developing countries. India bears 28.4% of the entire world's Tuberculosis burden. In 2020, 10 million people diagnosed with tuberculosis in India. About 1.5 million people died with tuberculosis in India[1]. Of these 3.5 million are sputum positive and each of them can spread the disease to 10-15 people they come in contact with. Each year 2.2 million people contract Tuberculosis. One Indian dies of Tuberculosis every minute. Five lakh people die of Tuberculosis in India every year by the disease which is curable. In 1992, WHO has declared tuberculosis a "global emergency" where half of world's population infected and died with Mycobacterium tuberculosis[2]. Although effective drugs are available for the treatment of tuberculosis prolonged duration of treatment and not taking the drugs regularly (i.e., non-compliance) and at appropriate dose has resulted in reduced cure rates and multi drug resistance. The recently introduced DOTS therapy as a part of RNTCP in India has the potential to ensure the compliance, increase the cure rates and reduce the incidence of Multi Drug Resistance[3]. Hence this study was taken up to evaluate the effectiveness of DOTS regimen in terms of cure rate, failure rate, defaulter rate and relapse rate, in the treatment of tuberculosis and also to know the influence of various secondary parameters like socio-economic status age non-compliance alcohol intake smoking and on the treatment outcome.

Methods

This study was conducted in Acharya Shri Chander College of Medical Sciences, Jammu and Kashmir from July 2021 and follow up period of 6 months after completion of treatment. Patients satisfying inclusion and exclusion criteria were included in this prospective study. Data was collected in a pre-tested proforma which includes various socio-economic parameters like age, occupation, sex, religion etc. Treatment cards maintained at DOTS center of ASCOMS hospital were also used. The age/sex distribution, clinical presentation, investigations and treatment categories and various outcomes were evaluated and compared with standard literature.

Statistical Analysis

Statistical methods: Cross tabs procedure (Contingency coefficient test), Descriptive statistics, Chi-square test, Repeated Measure ANOVA were applied in the present study.

All the statistical operations were done through SPSS for Windows, SPSS Inc. New York.

Results

Total of 60 patients were recruited for the study. Tuberculosis was most prevalent in 20-40 and 41-60 years in both sexes (Table 1). 50% (30 patients) and 28.3% (17 patients) respectively. Male:Female ratio was 1.14. 36 (60%) of the cases belong to poor socio-economic group and 24% belonged to middle class (Table 2). Cough, fever, night sweats, Weight loss, and hemoptysis were present in 46 (76%), 25 (41.7%), 22 (36.7%), 13 (21.7%) and 11 (18.3%) patients respectively (Table 3). Cervical lymphadenopathy was found in 9 patients of which 6 were females. Co-morbid illnesses noted were diabetes mellitus in 3 patients, IHD in 2 patients, HIV infection in 2 patients and COPD in 2 patients. There was history of alcohol consumption in significant amount in 8 patients. 18 patients were smokers. Chest X-ray abnormalities were noted in 47 (88.3%) upper lobe cavities was most common findings (Table 4). Of 60 patients 41 were classified as pulmonary cases as per RNTCP. Of 41 pulmonary cases 37 (90.2%) were sputum positive at presentation. 7 patients were sputum positive at the end of intensive phase of treatment. 3 patients were still sputum positive at the end of extended intensive phase. At the end of 2nd month of continuation phase 2 patients were sputum positive. At the end of treatment 3 patients were sputum positive. 32 (78%) patients were declared cured. 3 (7.3%) patients had failure (Table 5). Of these, 1 patient had HIV infections, 1 patient had Diabetes mellitus. 1 patient died during the course of treatment. He also had ischemic heart disease. 3 (7.3%) patients were declared completed treatment. Consumption of alcohol in significant quantity was more frequent among patients who had adverse outcome. Patients who were smokers had more adverse outcomes compared to non-smokers. Patients were followed up for 6 months and there was no relapse during the follow-up.

Discussion

In this study of 60 patients, pulmonary tuberculosis cases predominated and consisted of 41 (68.33%) cases and extra pulmonary cases accounted for 19 (31.66%) of the study group. Total number of male patients were 32 (53%) and female patients were 28 (48%) in the study group. Number of male patients in the pulmonary tuberculosis group was 23 (56%) and females were 18 (44%) Male:Female was 1.27. In a study by M Ejemez Corona et al, observed the Male: Female

ratio of 1.58[4]. Highest incidence of tuberculosis was observed in the age group was 21-40 years (50%) followed by 41-60 years age groups (28.3%) in both the sexes. In developing countries tuberculosis is prevalent in the age group of 15-59 years. In our study 36 (60%) belong to the low-socio economic group while 24 (40%) patients belong to the middle class. The association between tuberculosis and poor socio-economic status is well known. The majority, 90% to 95% do not progress further. However, in this study cure rate for pulmonary tuberculosis was 78%, failure rate was 7.3%, defaulter rate was 4.9%, there was no relapse and alcohol intake smoking, HIV infection, were associated with adverse outcomes.

Cough was present in 46 (70%) of the patient's fever present in 25 patients (41%), night sweats in 22 patients (36.7%), weight loss in 13 patients (21.7) and hemoptysis in 11 patients (18.3%) and chest pain was presenting symptom in 8 patients (13.3%) were present. William N Rom, and Stuart M Garay observed cough in 78%, weight loss in 74% on fever in 60%, night sweats in 55% and haemoptysis in 37% of their patients with tuberculosis[5].

Past history of tuberculosis was present in 8 (13.3%) patients. 5 patients have family history of tuberculosis in one of the family members. Cervical lymphadenopathy was noted in 9 patients of which 9 were females and 6 were male. Tubercular cervical of lymphadenitis tends to occur in females more often[6]. 3 patients had diabetes mellitus and 1 patient had HIV infection. Both these conditions are known to predispose the person per tuberculosis infection. 17 patients had pallor of mild to moderate degree. The cause of low hemoglobin in tuberculosis is multi factorial. Ebrahim recently found that the erythropoietin level was low in both in pulmonary tuberculosis and suggested that the blunted erythropoietin response in these patients was due to the inhibitory effect of tumor necrosis factor α (TNF α)[7]. Cavitations was seen in 19 (31.66%) patients. Upper lobe cavitations was more common. Woodring J H, Vandiviere HM, Fried AM et al observed cavitory lesions in 40-87% of the patient[8].

Among diabetes patients with pulmonary tuberculosis lower lobe involvement was seen in 2 patients (out of 3 diabetics). Weaver R has shown that tuberculosis occurs predominantly in the lower lung fields in case of diabetes[9]. 37 of the 41 pulmonary cases were found to be sputum AFB positive at presentation and 7 were positive at the end of the intensive phase. 3 patients positive for sputum AFB and 34 were negative at the end of 3 months of treatment. This data is comparable with that of status report on RNTCP in 2005[10]. Weight gain is an important clinical indicator of therapeutic response[11]. In our study average weight gain was 4 kg in cases of pulmonary tuberculosis. Whereas patients with adverse outcome did not gained weight at the end of the treatment. Of the pulmonary tuberculosis cases 32 (78%) patients were declared cured at the end of the treatment. 3 (7.3%) patients had failure; 1 patient had HIV infection with CD4+ count of 89 cells / cumm.

- 1 patient had diabetes mellitus.
- 2 (4.9%) patients defaulted.
- 1 patient died due to acute MI.

3 patients were sputum negative and at the end of treatment were declared completed treatment. In a meta-analysis short-course chemotherapy in pulmonary tuberculosis, Satagopan MC, Gupte MD, Murthy BN et al found average cure rate of 97.8%. Consumption of alcohol in significant quantities was more frequent among patients who had adverse outcome during therapy. Patients who were smokers also had adverse outcome compared to non-smokers. However, it was not statistically significant of the 19 extra pulmonary cases 1 patient died of liver cell failure and 18 patients were declared completed treatment. 1 patient had hepatitis and died during

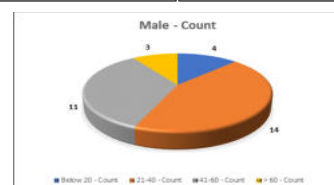
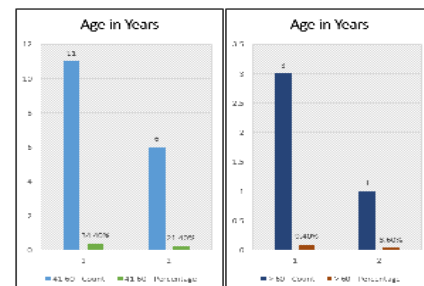
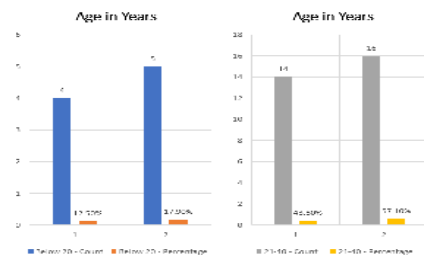
the course of treatment due to liver cell failure. 10 patient had gastrointestinal adverse effects which did not require discontinuation of therapy. Follow-up of patients was poor 80%, 60% and 50% at 1,3 and 6 months after treatment. There were no relapses among followed-up patients. However, relapse rate could not be ascertained because many patients did not attend for follow-up regularly. In a study by Jagota P et al observed a relapse rate of 5.8% after a follow-up of 6 months[12]. Clubbing was noted in 4 patients of these two patients had bilateral lung involvement. It is suggested that finger clubbing is of value in assessing patients with tuberculosis because it helps to identify those with severe destructive lung disease.

Conclusion

In our study cure rate of DOTS regime in pulmonary tuberculosis was 78%. Failure rate was 7.3% defaulter rate was 4.9% death rate was 2.4%. 7.3% of the pulmonary cases which were sputum negative for AFB were declared completed treatment. Among extrapulmonary cases 95% were declared completed treatment. 1 (5%) patient died due to Liver cell failure (drug induced due to Toxicity to Antitubercular drugs). Outcome patients with HIV infection (CD4+ < 200) and diabetes mellitus was poor compared to patients without these co-morbid conditions. 1 patient with HIV infection and 1 patient with diabetes mellitus had failure on DOTS regime. Alcoholics had adverse outcomes compare to people who were non-alcoholic patients.

Table 1: Distribution of Age and Sex

AGE in Years	SEX		Total
	Male	Female	
Below 20	4	5	9
	12.5%	17.9%	
21-40	14	16	30
	43.8%	57.1%	
41-60	11	6	17
	34.4%	21.4%	
> 60	3	1	4
	9.4%	3.6%	
Total	32	28	60
	100.0%	100.0%	



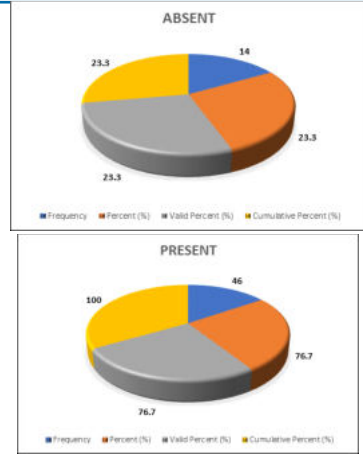
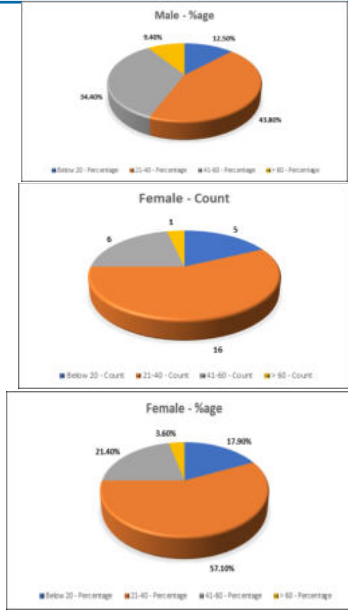


Table 2. Socio-economic status

	Frequency	Percent	Valid Percent	Cumulative Percent
Middle	24	40.0	40.0	40.0
Poor	36	60.0	60.0	100.0
Total	60	100.0	100.0	

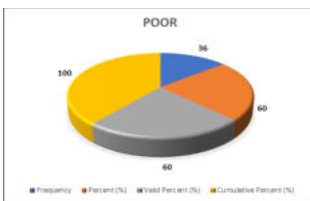
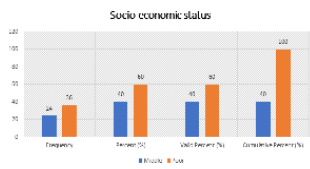
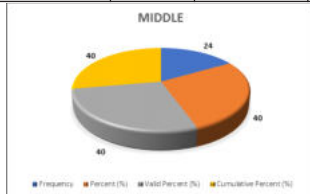


Table 3. Distribution of Cough

	Frequency	Percent	Valid Percent	Cumulative Percent
Absent	14	23.3	23.3	23.3
Present	46	76.7	76.7	100.0
Total	60	100.0	100.0	

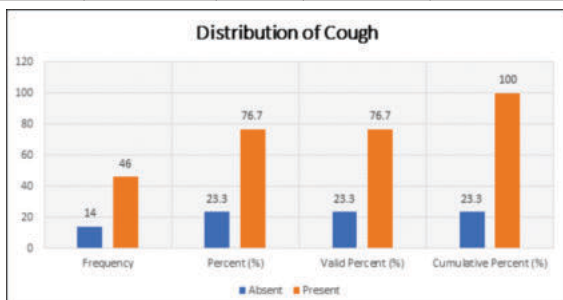


Table 4. X-Ray Findings

	Frequency	Percent	Valid Percent	Cumulative Percent
NORMAL	13	21.7	21.7	21.7
RUZ CON	6	10.0	10.0	31.7
LUC	1	1.7	1.7	33.3
BL CAV	2	3.3	3.3	36.7
RLZ	1	1.7	1.7	38.3
LUZ CON	8	13.3	13.3	51.7
LLZ CON	1	1.7	1.7	53.3
LEFT PE	6	10.0	10.0	63.3
RUZCAV	8	13.3	13.3	76.7
LUZ CAV	7	11.7	11.7	88.3
BL I	2	3.3	3.3	91.7
RUZ I	1	1.7	1.7	93.3
BL UZ CAV	2	3.3	3.3	96.7
LUZ PNEU	1	1.7	1.7	98.3
RIGHT PE	1	1.7	1.7	100.0
Total	60	100.0	100.0	

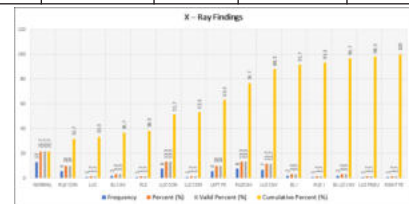
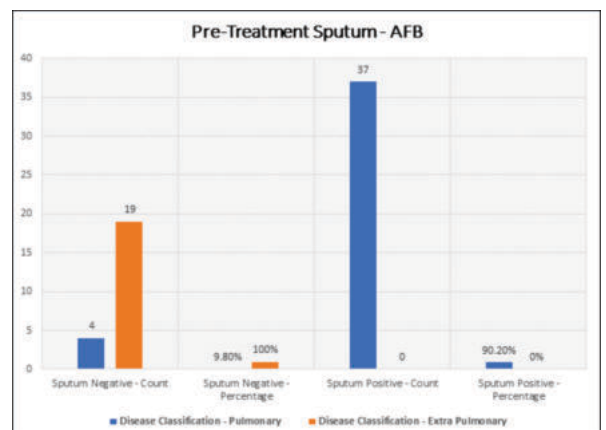
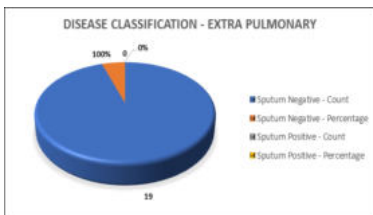
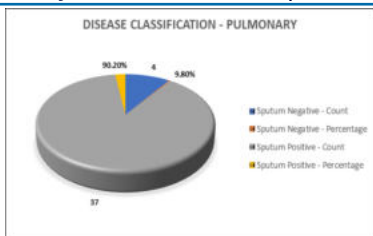


Table 5. Sputum Positivity

Pre-Treatment Sputum AFB	Disease Classification		Total
	Pulmonary	Extra Pulmonary	
Sputum Negative	4 (9.8%)	19 (100%)	23
Sputum Positive	37 (90.2%)	-	37
Total	41	19	60

C.C - 0.654 p < 0.000





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