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PROFILE OF SPUTUM POSITIVE PULMONARY TUBERCULOSIS PATIENTS ON RE-TREATMENT REGIMEN

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ABSTRACT: BACKGROUND: Tuberculosis (TB) is one of the most ancient diseases of mankind, with molecular evidence going back to over 17,000 years. In spite of newer modalities for diagnosis and treatment of TB, unfortunately, people are still suffering, and worldwide it is among the top 10 killer infectious diseases, second only to HIV. According to World Health Organization (WHO), TB is a worldwide pandemic. Tuberculosis is a major health problem in India also. DOTS treatment depends upon new case or previously treated case. A newly diagnosed case has success rate of 85% cure with DOTS regime, while the patient who were previously treated have success rate of 62%-70%. Therefore, Re-treatment cases (TB Patients who have been previously treated with anti-TB drugs for at least a month), are a challenge to this primary aim of the TB control Program. There are many risk factors which are related to treatment failure. In this study we would like to study the spectrum of disease related to relapse/failure/default and possible reasons why these patient had again developed tuberculosis by detailed history and clinical examination of patient. **METHODOLOGY:** Study was a cross sectional study of 100 patients with recurrent TB done in DOTS Centre in Government Wenlock hospital, DOTS Centre in KMC Attavar hospital. These patients were divided in three groups on the basis of Relapse, Failure and Default. Data obtain on the basis of history; clinical examination and investigation were compared at the end of study. **RESULTS:** Most of males were in the age group of 31- 40 years and female 31-40 years. Cough was present in 94.11% of patient and fever was present in 92.15% of patient, weakness in 80% and loss of appetite in 65%.52.9 %were Defaulters, 27.5% were "Treatment completed", 15.7% of patients were declared cured and 3.9 %of patients were Treatment failure cases.68 were smoker and 52 were alcoholic and 35 have both substance abuse. The incidence of anemia in our study was 86.75 %.10.8% of the patient have normal ESR and 95.1 %of patient blood were positive for CRP.42.1% of patient was having clinical evidence of pulmonary tuberculosis. 8% of patients were diabetics. **CONCLUSION:** Many factors are responsible for recurrence of pulmonary tuberculosis Patient with HIV and Diabetes Mellitus have high chances of recurrence of pulmonary tuberculosis due to decreased immunity. Defaulters have maximum chances of recurrence followed by Relapse cases. Treatment failure is uncommon cause of recurrent TB. Alcoholic are more likely to Default. ESR can be normal in recurrent pulmonary tuberculosis patients.
KEYWORDS: TB, DOTS.

INTRODUCTION: Tuberculosis (TB) remains a serious public health issue worldwide. Even in the era of effective chemotherapy, TB still accounts for a substantial number of deaths annually. Early diagnosis is challenging, even in areas with abundant medical resources.[1] In 2012, there were an estimated 12 million TB cases globally, including 8.6 million new cases, and 1.3 million fatal cases.[2]

The global case-fatality rates are reported to be between 7% and 35%,[3] and risk factors for death may include non-infective comorbidities, human immunodeficiency virus (HIV) infection and

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multidrug-resistant TB (MDRTB),[4] DOTS Treatment depends upon new case or previously treated case. A newly diagnosed case has success rate of 85% cure with DOTS regime, while the patient who were previously treated have success rate of 62%-70%.[5]

Therefore, Re-treatment cases (TB Patients who have been previously treated with anti-TB drugs for at least a month), are a challenge to this primary aim of the TB control Programme. When compared to new cases, re-treatment cases require longer and more complicated treatment, they are more likely to harbor & transmit drug-resistant TB, and are likely to have poor treatment outcomes, including increased risk of mortality.

There are many risk factors which are related to treatment failure. In this study we would like to study the spectrum of disease related to relapse/failure/default and possible reasons why these patient had again developed tuberculosis by detailed history and clinical examination of patient.

SUBJECTS AND METHODS: The study was a cross-sectional study carried out between September 2011 to august 2013 in DOTS centers of KMC hospital Attavar and Government Wenlock hospital and the sample size was 100. Study included patients who are sputum positive and previously treated for pulmonary tuberculosis. These patients were divided into 3 groups according to definition of Relapse, Failure and Default. Patients who are Sputum Positive and those who are previously treated cases for Pulmonary Tuberculosis with Anti-tuberculosis Therapy were included and Patients less than 14 year of Age were excluded.

RESULTS:

Age	Sex		Total
	Male	Female	
13-20 years	2	2	4
%	2.7%	8.3%	4.1%
21 -30 yes	16	6	22
%	21.6%	25.0%	22.4%
31 -40	20	12	32
%	24.3%	41.7%	32.6%
41 -50	17	3	20
%	23.0%	12.5%	20.4%
51 – 60	12	2	14
%	16.2%	8.3%	14.3%
>60	9	1	10
%	12.2%	4.2%	10.2%
Total	**76**	**26**	**102**
%	**100.0%**	**100.0%**	**100.0%**
Table 1: Showing the relation between Age and Sex in study subjects			

The mean age of the study subjects is 40.78 years with Standard Deviation of 15.531

Table 1 has shown frequency of study subject on the basis of Age and Gender. Maximum numbers of patient were male in age group of 31- 40 years followed by 21-30 year age group.

	Total	Minimum	Maximum	Mean	Std. Deviation
Age	102	16	83	40.78	15.531
Table 2: Descriptive Statistics of study patients					

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Table 2 has shown minimum age of subject was 16 in study group whereas; subject with maximum age was 83 with mean age of 40.78 and standard deviation of 15.531.

Termination of Treatment	Sex		Total
	Male	Female	
Default	39	15	54
%	50.0%	62.5%	52.9%
Treatment completed	26	2	28
%	33.3%	8.3%	27.5%
Declared cure	11	5	16
%	14.1%	20.8%	15.7%
Treatment Failure	2	2	4
%	2.6%	8.3%	3.9%
Total	**78**	**24**	**102**
%	**100.0%**	**100.0%**	**100.0%**
Table 3: Showing Reasons for Termination of Treatment			

Table 3 has shown that maximum number of patient in study group were Defaulter which constitute 52.9 %of total subjects. Relapse includes both treatment completed and those who declared cure constitutes 43.2% of total subjects whereas Treatment failure cases are 3.9%.

P value is <0.05 according to Fishers Exact test it suggest statistical significance.

History of Substance Abuse	Termination of Treatment				Total
	Defaulter	Treatment completed	Declared cure	Treatment failure	
NIL	17	7	6	3	33
% with h/o of substance abuse	51.5%	21.2%	18.2%	9.1%	100.0%
Alcohol	19	4	4	1	28
% with h/o of substance abuse	67.9%	14.3%	14.3%	3.6%	100.0%
Smoking	6	6	3	0	15
% with h/o of substance abuse	40.0%	40.0%	20.0%	.0%	100.0%
Both	12	11	3	0	26
% with h/o of substance abuse	46.2%	42.3%	11.5%	.0%	100.0%
Total	54	28	16	4	102
% with h/o of substance abuse	52.9%	27.5%	15.7%	3.9%	100.0%
Table 4: Showing History of substance abuse in study patients					

Chi square test =11.6, p =0.239.

P value <0.05 suggest statistical significance. There is significant correlation between Alcohol abuse and Defaulters.

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HIV Status	Sex		Total
	Male	Female	
Positive	7	4	11
% within sex	9.0%	16.7%	10.8%
Negative	71	20	91
% within sex	91.0%	83.3%	89.2%
Total	**78**	**24**	**102**
% within sex	**100.0%**	**100.0%**	**100.0%**
Table 5: Showing Relation between HIV Status and Sex			

HIV as a risk factor associated with recurrence of pulmonary tuberculosis is more in males as compared to females but the difference is found to be statistically insignificant.
Chi square test= 1.13, p = 0.288.

	Sex		Total
	Male	Female	
<18.5	15	9	24
%	18.8%	39.1%	24.9%
18.5-20	14	9	23
%	17.8%	21.7%	16.3%
20-22	11	4	15
%	15.9%	17.4%	16.3%
22-23.5	10	3	13
%	14.5%	13.0%	14.1%
>=23.5	25	2	27
%	36.2%	8.7%	29.3%
Total	**75**	**27**	**102**
%	**100.0%**	**100.0%**	**100.0%**
Table 6: Relation between BMI and Sex			

P value >0.05 suggest statistically non-significant. Chi square test =8.51, p = 0.075.
Although in our study BMI is having no significant correlation with the sex, BMI < 18.5 is more in females (39.17%) compared to males (18.88%). But obese (>23.5 BMI) is more in males (36.2%) compared with females (8.7%).

ANEMIA	MALE	FEMALE	Total
Present (%)	67(88.4)	22(84.6)	89
Absent (%)	9(11.8)	4(15.4)	13
Total	**76**	**26**	**102**
Table 7: Showing Anemia Correlation in study subjects			

Chi- square= 0.016, p= 0.899. P value >0.05 suggest statistically insignificant.

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Albumin	Sex		Total
	Male	**Female**	
<=3.5	74	20	94
%	94.8%	83.3%	92.1%
>3.5	4	4	8
%	5.2%	16.7%	7.9%
Total	**78**	**24**	**102**
%	**100.0%**	**100.0%**	**100.0%**
Table 8: Showing the level of Albumin in relation to SEX			

92.1% of patient had serum Albumin <3.5 gm/dl.

Chi-square = 3.38, p=0.066.

P>0.05 was statistically non-significant suggesting no significant difference between sex and serum albumin level.

	Sex		Total
	Male	**Female**	
Positive	74	23	97
%	94.9%	95.8%	95.1%
Negative	4	1	5
%	5.1%	4.2%	4.9%
Total	**78**	**24**	**102**
%	**100.0%**	**100.0%**	**100.0%**
Table 9: Showing relation between CRP and Sex			

Chi-square test= 0.364, p value =0.849.

Table 9 has shown that 95.1% of patient has positive CRP.

P >0.05 suggest statistical non-significance.

ESR	Sex		Total
	Male	**Present**	
<20	10	1	11
%	12.8%	4.2%	10.8%
>20	68	23	91
%	87.2%	95.8%	89.2%
Total	**78**	**24**	**102**
%	**100.0%**	**100.0%**	**100.0%**
Table 10: Showing the level of ESR in study subjects			

Chi –square test= 1.43, p= 0.232. Table 10 has shown that 10.8% of patient has <20 ESR on investigation.

P >0.05 suggest statistical non-significance.

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Peripheral Smear	Sex		Total
	Male	Female	
Normochromic Normocytic %	59	6	65
	75.6%	25.0%	63.7%
Microcytic Hypochromic %	19	18	37
	24.4%	75.0%	36.3%
Total %	**78**	**24**	**102**
	100.0%	**100.0%**	**100.0%**
Table 11: Showing the type of Peripheral Smear in Study Subjects			

P <0.05 suggest statistical significance. Table 14 shows P value of 0.000 suggest very highly significant correlation.

Chi-square test= 20.4, p value= 0.001

Table 11 has shown that Normocytic Normochromic peripheral smear picture was predominant finding in case of Males whereas Microcytic hypochromic peripheral smear picture was predominant finding in case of Females. By statistical analysis p value is 0.001 which is very highly significant.

SYMPTOM	Present	Absent	Total
Fever (%)	94(92.15)	8(7.8)	102
Cough (%)	96(94.11)	6(5.88)	102
Weight Loss (%)	48(47.05)	54(52.94)	102
Constitutional symptom (%)	64(62.74)	38(37.25)	102
Table 12: Showing frequency of Symptoms of Recurrent pulmonary TB			

Table 12 has shown that cough is most common symptoms of pulmonary tuberculosis followed by Fever. Constitutional symptoms were present in 62.74% of patients whereas weight loss was present in 47.05% of study group.

DISCUSSION: Out of 100 patients which were studied majority were males, Dooley et al.[5] had shown in their study that male sex is a risk factor for recurrent tuberculosis, this finding was consistent with our study. In our study male to female ratio was 3:1.

In our study patients cough was a predominant symptom and it was present in 94.11% of patient and fever was present in 92.15% of patient. This finding goes hand in hand with the study done by Dongre et al.[6] which has shown the following symptoms that were extracted in confirmed cases of tuberculosis[2]:

Cough – 96% of cases, Fever - 86% of cases, Weakness – 80% of cases, Loss of Appetite – 65% of cases. In our study 52.9 %were Defaulters, 27.5% were "Treatment completed", 15.7% of patients were declared cured and 3.9 %of patient were Treatment failure cases.

Substance abuse reduce cell mediated immunity hence increase tendency of retreatment regime. In our study there is significant correlation between alcohol abuse and defaulters.

The incidence of anemia in our study was 86.75 %which is much higher than 60% reported by Morris et al.[7]

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In our study only 10.8% of the patient had normal ESR. Al – Merri MR et al.[8] has shown that ESR was normal in one third of patient with pulmonary tuberculosis.

95.1 %of patient blood was positive for CRP. One Japanese study done by Yenagisava et al.[9] has shown that CRP was positive in 72% of patient with pulmonary tuberculosis. In our study 63.7 %of patient peripheral smear suggestive of normocytic normochromic anemia and   it was stastically significant and 36.3% of patients show microcytic hypo chromic anemia. Edward et al.[10] has shown in their study normocytic normochromic anemia was present in 95% of patients.

Iron deficiency anemia contribute significant percentage of anaemia in comparision with anemia of chronic disease. In our study Nutritional anemia contributes significant percentage of anaemia in comparison with previous studies.

92.1% of patient had serum albumin <3.5 gm/dl. This suggests strong negative correlation of albumin with recurrent pulmonary tuberculosis. Kado et al.[11] has shown significant negative correlation between serum albumin and relapse in pulmonary tuberculosis.

CONCLUSION: Defaulters have maximum chances of recurrence followed by Relapse cases. HIV and Diabetes mellitus patients have high chances of recurrence.

Treatment failure is uncommon cause of recurrent TB. Alcoholic are more likely to Default. ESR can be normal in recurrent pulmonary tuberculosis patients.

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