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FACTORS INFLUENCING THE BACILLARY LOAD AMONG SPUTUM POSITIVE CATEGORY I DOTS TUBERCULOSIS CASES IN DISTRICT ROHTAK, HARYANA

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ABSTRACT

Background: Tuberculosis remain one of the major public health problem. Many studies document that a high pre-treatment bacillary load can lead to poor outcomes. Objective: The present study was undertaken to determine pre-treatment smear grading among New Sputum Positive Tuberculosis patients and to determine factors that are associated with high pre-treatment (3+) smear grading. Design: It was a cross-sectional study for 12 months and NSP TB cases, who were to start their Category I treatment regimen at DTC, DOTS Centre, were recruited. After enrolment, various parameters were studied (recorded) on a predesigned, pre-tested, semi-structured schedule. Results: The study had 71.3% males and 28.7% females. Nearly, half (49.5%) of the subjects had a high pre-treatment bacillary load (3+). On logistic regression consumption of tobacco and duration to reach DOTS treatment were found to be independently associated with increased pre-treatment bacillary load of the disease with an odd's ratio of 2.405 and 3.726 respectively Conclusion: The consumption of tobacco and duration of the patient reaching the RNTCP treatment influence pre-treatment bacillary load. It is recommended to adopt health life style by a complete halt of tobacco smoking and active screening of TB patients to reach the unreached within appropriate time frame.

Key words: Sputum Conversion, tobacco, smoking, pre-treatment bacterial load, tuberculosis.

INTRODUCTION

Tuberculosis (TB) is a disease of antiquity, it should not be misinterpreted as a disease of the past as it is set to rekindle its dominance in the near future with its coexistence with Human Immunodeficiency Virus (HIV) and emergence of Multi Drug Resistant (MDR)-organisms. Millennium development goals (MDG) targets to eliminate TB as a public health problem by 2050 and to halt and reverse the prevalence and mortality by 50% in comparison to 1990 by 2015.[1]

Globally, the TB mortality rate has fallen by 45% since 1990 and the Stop TB strategy target is within reach. TB incidence has been falling globally for several years (1.5% per year from 2000 to 2013). There is a great opportunity for innovative approaches to ensure that everyone suffering from TB has access to TB diagnosis, treatment and cure. [1]

India alone accounts for 24% of the total cases.[1] TB is one of the leading causes of mortality in India killing 2 persons every three minute, nearly 1,000 every day.[2]

In 2013, the annual incidence of TB was estimated to be 171 per lakh and prevalence was estimated to be 211 per lakh accounting to a total 1252 million including the new as well as relapse cases. [1] With a single open case infecting an 10-15 individuals, it will rekindle its place with a great amount of burden on the Indian society in the near future.[3] In 2013, Haryana had 25,629 smear positive TB cases while district Rohtak had 2,278 smear positive TB cases. According to District level Household survey (DLHS) IV, Haryana and Rohtak had a prevalence of 1.3% and 1.4% respectively. [4]

The sputum conversion rate (SCR) is the percentage of smear-positive pulmonary TB cases registered in a specified period that converted to smear negative status after the standard two months of the intensive phase of treatment. WHO recommends its use as a useful indicator for TB control programs in monitoring the TB program

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performance, and as a trigger for rigorous assessment in patients with still positive smear? Even in well-functioning national TB programs 25% of initially smear-positive pulmonary TB patients may still be smear-positive at the end of the intensive phase of treatment, despite good adherence and supervised medication. [5] Infection control measures such as use of mask are to be maintained until non-infectiousness has been demonstrated.

Many studies have documented that a high pretreatment bacillary load can lead to poor outcomes. [6-12]

The present study was undertaken to determine high pre-treatment smear grading among TB patients and to determine factors that are associated with high pre-treatment smear grading.

MATERIALS AND METHODS

The study was conducted by Department of Community Medicine, Post Graduate Institute of Medical Sciences at the District Tuberculosis Centre (DTC), Rohtak (Haryana). It also has diagnostic microscopic facilities and RNTCP trained Laboratory technicians for appropriate diagnosis of TB. The DOTS centre functioning at DTC itself was selected for the purpose of feasibility of the study.

The study subjects comprised of New Sputum Positive (NSP) TB patients in Category I as per Revised National Tuberculosis Control Programme (RNTCP) guidelines attending the DTC, DOTS Centre, Rohtak, who were ≥ 15 years of age. The pre-diagnosed NSP TB cases were enrolled from DTC, DOTS Centre over a period of 12 months with a minimum of 100 study subjects depending on availability. This was a cross-sectional study and conducted for a period of one year, from October 2013 to September 2014. Those who were not willing to give informed written consent, age < 15 years, smear negative cases and extra pulmonary cases were excluded from the study.

The NSP TB cases, who were to start their Category I treatment regimen at DTC, DOTS Centre, were recruited and an informed written consent was taken. After enrolment, various parameters were studied (recorded) on a predesigned, pre-tested, semi-structured schedule with various parameters on Socio Economic Status (Modified Kuppuswamy Scale), consumption of tobacco [13] and alcohol [13] and duration to reach DOTS treatment. The results of pre-treatment sputum specimen were recorded. Permission was granted by the State TB Officer for carrying out the study at DTC. Ethical principles such as obtaining consent were adhered.

Data obtained was coded and entered using Microsoft Excel 2013. The statistical tests were performed at a 5% level of significance, thus an association was significant if the p value was less than 0.05. Categorical variables were analysed by Pearson chi-square test and Odd's Ratio (OR) was calculated and logistic regression was applied.

RESULTS

The mean age of the study participants was 36.19 ±15.88 years. The study had 71.3% males and 28.7% females with a mean age of 37.91 ±15.94 and 31.89 ± 15.17 years, respectively. More than half (55.4%) of the subjects were in the age group of 15-34 years. Nearly, two third (62.4%) & one third (34.7%) of the subjects had a total family income of less than Rs 10,000 and Rs 10,000 - 50,000 on a monthly basis.(Table 1) Nearly, two third (62.4%) of the study subjects were of upper lower SES and more than one fourth (28.7%) of the subjects were of lower middle SES. (Table 2)

Table 2 : Distribution of the study subjects according to Socio economic status(Modified Kuppuswamy Scale)

Socio economic status			
Upper	1(1.4)	0(0)	1(1)
Upper middle	4(5.6)	2(6.9)	6(5.9)
Lower Middle	23(31.9)	6(20.7)	29(28.7)
Upper Lower	42(58.3)	21(72.4)	63(62.4)
Lower	2(2.8)	0(0)	2(2)
Total	72(100)	29(100)	101(100)

Nearly, half (49.5%) of the subjects had a pre-treatment bacillary load of 3+ and more than one fourth (29.7%) of the subjects had a bacillary load of 1+ and one tenth (11.9%) of the subjects had 2+ and rest had scanty.(Table 3)

Table 3: Distribution of the study subjects according to pre-treatment sputum smear grading

Pre-treatment sputum smear grading	
Scanty	9(8.9)
1+	30(29.7)
2+	12(11.9)
3+	50(49.5)

(The values in parentheses indicate percentage)

Table 1 : Socio-demographic profile of the study participants

Age group (years)	Gender		Total
	Male	Female	
15-24	18(25)	10(34.5)	28(27.7)
25-34	17(23.6)	11(37.9)	28(27.7)
35-44	12(16.7)	1(3.4)	13(12.9)
45-54	13(18.1)	4(13.9)	17(16.9)
55-64	6(8.3)	1(3.4)	7(6.9)
≥65	6(8.3)	2(6.9)	8(7.9)
Category			
Scheduled Caste (SC)	43(59.7)	18(62.1)	61(60.4)
Scheduled Tribe (ST)	3(4.2)	1(3.4)	4(4.0)
Other Backward Class (OBC)	17(23.6)	8(27.6)	25(24.8)
Others	9(12.5)	2(6.9)	11(10.8)
Type of Family			
Nuclear	50(69.4)	20(69)	70(69.3)
Joint	22(30.6)	9(31)	31(30.7)
Total Family Income (Rs)			
<10,000	42(58.3)	21(72.4)	63(62.4)
>10,000	30(41.7)	8(27.6)	38(37.6)
Occupation			
Labourer	33(45.8)	6(20.7)	39(38.9)
Agriculture	8(11.1)	0(0)	8(7.9)
Student	9(12.5)	10(34.5)	19(18.8)
Housewife	0(0)	13(44.8)	13(12.6)
Private job	12(16.7)	0(0)	12(11.9)
Govt. Job	3(4.2)	0(0)	3(3)
Others	7(9.7)	0(0)	7(6.9)
Socio economic status			
Upper	1(1.4)	0(0)	1(1)
Upper middle	4(5.6)	2(6.9)	6(5.9)
Lower Middle	23(31.9)	6(20.7)	29(28.7)
Upper Lower	42(58.3)	21(72.4)	63(62.4)
Lower	2(2.8)	0(0)	2(2)
Total	72(100)	29(100)	101(100)

(The values in parentheses indicate percentage)

Pre-treatment bacillary load

For the purpose of analysis, 3+ sputum smear has been graded as high bacillary load and rest (2+, 1+ and scanty) were graded as low bacillary load.

Majority (76%) of the subjects with high bacillary load were males and rest (24%) were females. About two third (68%) of the study subject with high bacillary load were below the age of 40 years and rest (32%) were above 40 years as compared to similar distribution (52.9% & 47.1%) among subjects with low bacillary load. More than half (56%) of the subjects with high bacillary load had a total family income of less than Rs 10,000 as compared to the two third (68.6%) of the subjects with low bacillary load. About four fifth (44%) of the subjects with high bacillary load were engaged in the manual labour as compared to 33.3% in subjects with low bacillary load. Among subjects with low bacillary load and high bacillary load, upper lower status constituted 70.6% and 54% of the subjects respectively. It was not statistically significant as p value $\geq$0.05.(Table 4)

Among the high bacillary load, 10% and 5.9% in the subjects with low bacillary load had diabetes. It was found to be positive in 46% of the subjects with high bacillary load and 51% of the subjects with low bacillary load. One fifth (20% & 17.6%) of the subjects with high bacillary load and low bacillary load had a positive family history. These factors found to be statistically non-significant. The subjects with high bacillary load had a history of consumption of tobacco in more than two third (70%) of the subjects as compared to 33.3% in low bacillary load and was found to be statistically significant with an odd's ratio 4.6. majority (84.3%) of the subjects with low bacillary load had duration of the symptoms less than 6 months and 44% of the subjects with high bacillary load had a duration of symptoms more than 6 months and was found to be statistically significant.(Table - 5)

On logistic regression consumption of tobacco and duration to reach DOTS treatment were found to be independently associated with increased pre-treatment bacillary load of the disease with an odd's ratio of 2.405 and 3.726 respectively. (Table 6)

DISCUSSION

Males and females were in the ratio of 2.5:1. Two third (67.3%) of the subjects were in the age group of 15 - 44 years of age which is quite similar to the global data of 59% in 2013.[1]The various studies across the globe also had a similar finding that was dominated by TB patients between their productive age groups such as Jianzhao et al among the community of China, Mota et al in the Portugal, Tiwari et al in New Delhi and Bouti et al in Morocco found that majority of the TB smear positive patients were from the most productive age group of life i.e. between 20-41 years.[14-17]

In the present study, one third (34%) subjects with high bacillary load and almost one fourth (23.5%) subjects with low bacillary load belonged to lower middle SES. The finding was similar to

Table 4: Association of socio-demographic factors and pre-treatment smear grading.

Socio-demographic factors	High bacillary load (3+)	Low bacillary load (2+,1+and Scanty)	Total	p value
Gender				
Female	12(24)	17(33.3)	29(28.7)	χ^2 =1.074, df=1
Male	38(76)	34(66.7)	72(71.2)	p = 0.300
Age Group				
<40	34(68)	27(52.9)	61(60.4)	χ^2 =2.39, df=1
≥40	16(32)	24(47.1)	40(39.6)	p = 0.122
Education				
Literate	38(76)	38(74.5)	76(75.2)	χ^2 =2.57, df=6
Illiterate	12(24)	13(25.5)	25(24.8)	p = 0.862
Total Family income per month(in Rs)				
<10,000	28(56)	35(68.6)	63(62.4)	χ^2 =2.48, df=3
>10,000	22(44)	16(31.4)	38(37.6)	p = 0.478
Occupation				
Labourer	22(44)	17(33.3)	39(38.6)	χ^2 =3.18, df=6
Agriculture	4(8)	4((7.8)	8(7.9)	p = 0.785
Student	9(18)	10(19.6)	19(18.8)	
Housewife	5(10)	8(15.7)	13(12.9)	
Private job	4(8)	8(15.7)	12(11.9)	
Govt. Service	2(4)	1(2)	3(3)	
Others	4(8)	3(5.9)	7(6.9)	
Socio economic status				
Upper	1(2)	0(0)	1(1)	χ^2 =5.138, df=4
Upper middle	3(6)	3(5.9)	6(5.9)	p = 0.273
Lower Middle	17(34)	12(23.5)	29(28.7)	
Upper lower	27(54)	36(70.6)	63(62.4)	
Lower	2(4)	0(0)	2(2)	
Total	50(49.5)	51(50.5)	101(100)	

Tiwari et al who observed that 75.1% patients of high bacillary load cohort and 66.3% patients of low bacillary cohort fall in the upper lower category. [18] Gupta et al in India, found that OR increased by 3.14 (95% CI 2.48-3.98, p<0.001) for every decrease of Rs.500/- in the income level per person per month below Rs.2, 000/-. Similarly, the OR increased by 3.66 (CI 2.9-4.61, p < 0.001) with increasing number of persons per room. [19]

In the present study, amongst those with high bacillary load two fifth (44%) were labourers as compared to 33.3% low bacillary load but this association between occupation and bacillary load was non- significant. Muniyandi et al observed that in India, 64% of patients taking treatment under TB control programme were from poor economic strata. [20]

Among subjects with high pre-treatment bacillary load, more than two third (70%) of the subjects had a history of consumption of tobacco as compared to 33.3% in low pre-treatment bacillary load and was found to be statistically significant with an odd's ratio 4.6. Matsumoto et al in Osaka city reported that sputum smear grades (2+) and (3 +) were significantly correlated with being a smoker. [21]

Various studies show there is also strong influence of heavy drinking on the clinical course of TB. [22-26] In the present study, consumption of alcohol was found in two fifth (40.6%) of the subjects and nearly two fifth (42% and 39.2%) in both the groups of high and low pre-treatment bacillary load with an OR = 1.12 but was non-significant. This could be due different socio demographic settings.

Ideally, symptoms of 2 weeks is enough for a person to be a TB suspect but in the present study , it was seen more than one fourth (29.7%) of the subjects had symptoms of over 6 months before seeking initiation of treatment inferring that there is a considerable delay in taking the TB suspects to DOTS. It was also found that the duration to reach

Table 5: Association of pre-treatment smear grading and history of TB patient

Consump-tion of tobacco	High bacillary load(3+)	Low bacillary load (2+,1+, Scanty)	Total	p value
Yes	35(70.0)	17(33.3)	52(51.5)	$\chi2$ =13.59, df=1
No	15(30)	34(66.7)	49(48.5)	p = 0.001 OR=4.6
Consumption of alcohol				
Yes	21(42)	20(39.2)	41(40.6)	$\chi2$ =0.081, df=1
No	29(58)	31(60.8)	60(59.4)	p = 0.776 OR=1.12
History of Diabetes				
Yes	5(10)	3(5.9)	8(7.9)	$\chi2$ =0.001, df=1
No	45(90.0)	48(94.1)	93(92.1)	p = 0.977 (OR=1.02)
BCG Status				
Yes	23(46)	26(51)	49(48.5)	$\chi2$ =0.25, df=1
No	27(54)	25(49)	52(51.5)	p = 0.617 (OR=0.96)
Family history of TB				
Yes	10(20)	9(17.6)	19(18.8)	$\chi2$ =0.092, df=1
No	40(80)	42(82.4)	82(81.2)	p = 0.762 (OR=1.167)
Duration to reach RNTCP DOTS treatment				
< 6 months	28(56.0)	43(84.3)	71(70.3)	$\chi2$ =9.69, df = 1
>6 months	22(44.0)	8(15.7)	30(29.7)	p = 0.002
Total	50(49.5)	51(50.5)	101(100)	(OR=0.226)

Table 6: Logistic regression on the variable influencing the pre- treatment bacillary load

Variables	B Co-efficient	P value	Exp(B)	Lower limit of Exp (B)	Upper limit Of Exp(B)
Consump-tion of tobacco	0.877	0.42	2.405	1.031	5.607
Duration to reach DOTS facility	1.315	0.07	3.726	1.417	9.724

DOTS had a significant effect on bacillary load as 44% of the subjects with high bacillary load had a duration of more than 6 months thus increasing the severity of the disease. The most probable reason for this delay might be due to the reason that TB patients are prone to multi consultations for the disease and are put on multi treatment regimens before they are on RNTCP DOTS regimen.

CONCLUSION

It is concluded that the high pre-treatment load is dependent on consumption of tobacco and duration of the patient reaching the RNTCP treatment. To improve the outcome of the patient, it is recommended to adopt health life style by a complete halt of tobacco smoking. With India achieving its RNTCP objectives there is serious need to start active screening of TB patients to reach the unreached within appropriate time frame.

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