Comparison of Treatment Outcomes among Tuberculosis Patients with HIV and Without HIV Infection in a Metropolitan City

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ABSTRACT

Background: Tuberculosis (TB) is a major public health problem. Along with HIV infection, it forms a deadly combination and those with these diseases are seen to have unfavourable outcomes.

Objectives: 1)To study the clinical profile of TB patients with HIV and without HIV co- infection. 2) To find the treatment outcome among the groups. 3) To compare treatment outcomes of patients between the groups. 4) To assess associated factors influencing treatment outcome in both groups.

Methodology: The study group included sero positive Tuberculosis patients, while the control group included sero negative Tuberculosis patients. They were enquired about their demographic profile, socio-economic status, past and present TB history including their treatment details and treatment outcome. Additional information regarding the basic CD4 count diagnosis and Anti-Retroviral Therapy (ART) was collected from the study group.

Important Findings: Tuberculosis was more commonly seen in lower socioeconomic group, less educated and economically most productive group. Common symptom seen was fever, cough and weight loss. More prominent signs and symptoms were seen in seropositive patients. Weight gain was more significant in the control group. Treatment outcome was favourable among sero negative patients.

Conclusion: Treatment outcome of tuberculosis patients on DOTS regimen depends on the HIV status of the patient.

Key Words: Tuberculosis, DOTS therapy, HIV infection, treatment outcome.

INTRODUCTION

Tuberculosis (TB) remains a major global health problem. It causes ill-health among millions of people each year and ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV)[1].

Tuberculosis and HIV duo forms the deadly synergy. Treatment outcomes of tuberculosis patients with HIV infection have not been favourable. HIV infection increases the risk of progression of latent TB infection to active TB disease thus increasing risk of death if not timely treated for both TB and HIV. Correspondingly, TB is the most common opportunistic infection and cause of mortality among people living with HIV (PLHIV)[2].

HIV/TB together have extremely high death rates (15 to 18%) reported among HIV infected TB cases notified under Revised National TB Control Programme (RNTCP).

Overall, TB is estimated to cause about 25% of all deaths among PLHIV in India. Early detection of

HIV/TB cases and prompt provision of Anti-Retroviral Treatment (ART) and Anti-TB Treatment (ATT) are key interventions to reduce mortality rates significantly[3].

The present study was therefore proposed to study the treatment outcome of tuberculosis in patients co-infected with HIV and its comparison with those without HIV infection in patients at an ART centre and selected DOTS centres.

OBJECTIVES

The research was conducted to study the clinical profile of TB patients co-infected with HIV (study group) and patients without HIV co-infection (control group) and also to find out the treatment outcome of DOTS in TB-HIV co-infected patients and compare it with that of HIV negative patients. The study was also aimed to assess the associated factors influencing treatment outcome in both study and control group.

METHODOLOGY

This study was carried out in a randomly selected TB administrative zone, out of the six zones of a metropolitan city. The selected zone consists of 108 DOTS centres and one ART centre. 10% of 108 i.e. 10 DOTS centres were selected randomly. These 10 DOTS centres and an ART centre attached to a secondary care hospital of the above mentioned TB zone were the study site. TB patients attending the above mentioned study site were the study population.

The study was conducted in the first two quarter of the year 2013 (i.e. 1st January 2013 to 30th June 2013).

The patients were divided into 2 groups, study group and control group.

Group 1: The study group included HIV positive patients attending ART OPD, diagnosed as Tuberculosis and started on DOTS therapy for the same in the study period.

Group 2: The control group included patients registered at randomly selected DOTS centres in the study area, which were diagnosed and started on DOTS therapy and found negative on HIV testing for the same in the study period. Care was taken to include patients preferably of the same age group as the study group.

Critically ill patients for whom OPD basis treatment was not advisable were not included in the study. Patients who are not willing to participate in the study were also excluded.

METHODOLOGY

Institutional Ethics committee approval was taken before the start of the study. The new TB patients who fulfilled the above mentioned criteria were included in the study. The study group was selected by visiting the ART centre, while the control group from the DOTS centres. Informed written consent was taken from all the patients, who were interviewed with a pretested semi structured interview schedule, which included, their demographic profile, socio-economic status, past and present TB history including their treatment details and treatment outcome. In TB-HIV co-infected patients, information regarding the basic CD4 count at the time of TB diagnosis and Anti-Retroviral Therapy (ART) was also collected.

Patients involved in the study were followed up for a period of at least 6 months to a maximum of one year, till the treatment outcome was declared.

Patients were followed up by catching up at the DOTS or ART centre. Basic parameters used for follow up were: clinical improvement, weight gain, sputum conversion. During this phase, each interaction with the patient either at home or at DOTS centre was used as an opportunity to educate the patient and his/her relatives. Patient and their relatives were educated about the importance of proper nutrition, hygiene, control and prevention of TB and HIV with special emphasis on adherence to treatment.

Data analysis: After checking for completeness, the data was entered in Microsoft Office Excel sheet, where it was filtered, processed and edited. The data was further analysed using SPSS 20 analysis software. Tables and graphs were drawn, where necessary. Chi square test and t- test for association and distribution was used for statistical analysis.

RESULTS

All the patients who completed their follow up were only included in the final analysis. Hence, a total of 178 patients were part of our study. Out of 178 patients, 88 were seropositive (HIV positive status, study group), while 90 were sero-negative (HIV status-negative, control group). In both the groups, maximum patients were in 21 to 40 years age group. Mean age of seropositive TB patients was 38.42 years (standard deviation: 9.48, range: 18-65 years) while it was 33.96 years for sero-negative TB patients (standard deviation: 13.64 years, range: 16-75 years). Male to female ratio was on higher side in seropositive patients (2:1 to 1:2) than in control group. Majority of patients were Muslims (52.80%) followed by Hindus (40.45%).

Table 1: Demographic Profile of the TB cases

Demographic profile	Serostatus of TB cases		Total
	Positive (n=88) (%)	Negative (n=90) (%)	
Age (yr)			
Up to 20	4(4.54)	11(12.22)	15(8.43)
21-30	15(17.04)	38(42.22)	53(29.78)
31-40	38(43.18)	16(17.78)	54(30.33)
41-50	23(26.14)	14(15.56)	37(20.78)
>50	8(9.1)	11(12.22)	19(10.68)
Sex			
Male	59(67.05)	31(34.44)	90(50.56)
Female	29(32.95)	59(65.56)	88(49.44)
Religion			
Hindu	57(64.77)	15(16.66)	72(40.45)
Muslim	22(25)	72(80)	94(52.80)
Others	9(10.23)	3(3.34)	12(6.75)
Marital status			
Single	12(13.64)	13(14.45)	25(14.04)
Married	65(73.86)	77(85.55)	142(79.78)
Other*	11(12.5)	0	11(6.18)
Education			
Illiterate	20(22.72)	30(33.34)	50(28.08)
Up to primary	07(7.95)	25(27.77)	32(17.97)
Secondary	22(25)	22(24.45)	44(24.72)
Higher Secondary	15(17.05)	08(8.88)	23(12.93)
Graduate & above	24(27.28)	05(5.56)	29(16.30)
Occupation			
Unemployed	37(42.04)	56(62.22)	93(52.25)
Unskilled	32(36.36)	20(22.22)	52(29.22)

*Included Widow/divorced/ separated

Table 2: Clinical profiles of Tuberculosis patients

Signs and symptoms	Serostatus of TB Cases		Total
	Positive(%)	Negative(%)	(%)
Cough	49(55.68)	67(74.44)	116(65.16)
Fever	59(67.04)	63(70)	122(68.53)
Weight loss	54(61.36)	26(28.88)	80(44.94)
Haemoptysis	06(6.81)	02(2.22)	08(4.49)
Lymphadenopathy	12(13.63)	13(14.44)	25(14.04)
Abdominal pain	05(5.68)	04(4.44)	9(5.05)

Table 3: Physical Examination finding

Examination findings	Serostatus of TB Cases		Total
	Positive(%)	Negative(%)	(%)
Pallor			
Yes	57 (64.77)	65(72.22)	122 (68.54)
No	31 (35.23)	25 (27.78)	56 (31.46)
Lymphadenopathy			
Yes	12 (13.64)	13 (14.44)	25 (14.04)
No	76 (86.36)	77 (85.56)	153 (85.96)
Respiratory system			
NAD	57 (64.77)	76 (84.45)	133 (74.72)
Abnormal	31 (35.23)	14 (15.55)	45 (25.28)
Per abdomen			
NAD	82 (93.18)	88 (97.77)	170 (95.50)
Abnormal	06 (6.82)	02 (2.23)	08 (4.50)

Most of them were married. However 12.5% seropositive TB patients were widowed separated or divorced. (12.5 vs 0: X^2 = 12.0331, df = 2, p = 0.002: significant).

In seropositive TB patients, 27.28% completed their education up to graduation or above followed by secondary school (25%). Most of the patients in the control group were illiterate, followed by education till primary and secondary school.

Unemployment was more in control group, but this figure is inflated because of inclusion of housewives, students and retired persons which was 28, 12 and 5 respectively. In seropositive patients, 13 housewives and 5 students were recruited.

Most of the seropositive TB patients belonged to class II (34.10%) while most of the seronegative patients belonged to class IV (52.22%) of modified B. G. Prasad socioeconomic class.

Overall the most common presenting symptom in TB patients was fever (68.53%). However cough (74.44%) was more common in seronegative TB patients, while fever (67.04%) was the most common presenting feature in seropositive TB patients.

On performing thorough general examination of the Tuberculosis patients, it was found that pallor was very prevalent in both the groups accounting for 68.54 % in total. The prevalence of lymphadenopathy was found to be almost equal in both the groups with the most common site being cervical nodes (61.53 % in control group and 83.34% in study group). Respiratory system findings like presence of crepts, rhonchi and diminished air entry on auscultation were significantly more in study group (X^2 = 9.115, df = 1, p = 0.002).

Out of 88 HIV-TB co-infected patients, 10 (11.36%) had a past history of Tuberculosis. While 27 (30%) of seronegative patients had past history of Tuberculosis.

Of the 10 patients of the study group who had past history of TB, 9 (90%) had suffered from pulmonary disease while one had history of extrapulmonary TB. In control group, 23 (88.46) patients had pulmonary TB and 3 (11.54%) had extrapulmonary TB.

In both the groups, main source of treatment was DOTS centre (90% in study and 84.62% in control group). More than 2/3rd of the patients in both the groups completed the treatment for recommended duration. Favourable treatment outcome in study and control group was 60% and 73.07% respectively. In study group, there were 3 (75%) failures and 1(25%) defaulter, while in control group, all the 7 (100%) were defaulters.

In both the groups, the predominant type of Tuberculosis was Pulmonary (55.68% in study group and 73.33% in control group). Majority (73.03) of patients in both the groups were started on Cat I.

Table 4: Characteristics of the present Tuberculosis Infection

Disease characteristic	Serostatus of TB Cases		Total (n=178)(%)
	Positive (n=88)(%)	Negative (n=90) (%)	
Type of TB			
Pulmonary	49 (55.68)	66 (73.33)	115 (64.6)
Extra pulmonary	39 (44.32)	24 (26.67)	63 (35.4)
DOTS category			
I	67 (76.14)	63 (70)	130 (73.03)
II	21 (23.86)	27 (30)	48 (26.97)
Pre treatment sputum			
Positive	32 (36.36)	37 (41.11)	69 (38.76)
Negative	56 (63.64)	53 (58.89)	109 (61.24)
Type of case			
New	67 (76.13)	63 (70)	130 (73.04)
Relapse	06 (6.81)	08 (8.89)	14 (7.86)
Treatment after Default	03 (3.4)	06 (6.67)	09 (5.06)
Failure	01 (1.13)	0	01 (0.56)
Other	11 (12.5)	13 (14.44)	24 (13.48)

Table 5: Tuberculosis treatment outcome in both the groups

Treatment outcome	Serostatus of TB cases		Total (n=178)(%)
	Positive (n=88)(%)	Negative (n=90) (%)	
Cured	24 (27.27)	30 (33.34)	54 (30.34)
Completed	45 (51.13)	52 (57.78)	97 (54.50)
Failure	03 (3.4)	00 (0.00)	03 (1.68)
Defaulter	00 (0.00)	03 (3.33)	03 (1.68)
Died	06 (6.81)	01 (1.11)	07 (3.94)
Transferred out	02 (2.27)	01 (1.11)	03 (1.68)
Shifted to MDR	08 (9.10)	03 (3.33)	11 (6.18)

Table 6: Factors associated with Tuberculosis Outcomes in both the groups.

Factors	Treatment Outcome		P Value
	Cured & Completed	Others	
Serostatus of TB Patients			
Seropositive	69 (78.40)	19 (21.60)	**0.018**
Seronegative	82 (91.12)	8 (8.88)	
DOTS category			
I	54(80.6)	13(19.4)	**0.372**
II	15(71.42)	06(28.58)	
Pre-treatment Sputum Examination			
Positive	57 (78.26)	12 (17.40)	**0.510**
Negative	94 (86.20)	15 (13.8)	
Patients taking ART			
Yes	39 (73.58)	14 (26.42)	**0.175**
No	30 (85.72)	05 (14.28)	
CD4 count at start of treatment			
<200	20 (62.5)	12 (37.5)	**0.018**
200 – 350	20 (83.34)	04 (16.66)	
>350	29 (90.62)	03 (09.38)	

*P<0.05 indicate statistical significance

Pre-treatment sputum AFB was positive in 36.36% of HIV-TB co-infected patients. In control group, pre-treatment sputum AFB was positive in 41.11% patients.

In our study, the commonest site of extra-pulmonary TB in HIV-TB co-infected patients was found to be pleural effusion (46.16%) followed by lymph nodes (28.20%) and abdominal TB (17.94). In the study group, most commonly involved lymph nodes were cervical (in 9 out of 11) followed by axillary nodes in remaining 2 patients. In control group, the commonest site of extra-pulmonary TB was found to be lymph nodes (50%) followed by pleural (29.16%) and abdominal TB (12.5%). Cervical nodes were affected in 11 cases while there was one case of axillary lymphadenopathy. The study suggests that tuberculosis pleural effusion was more common in HIV-TB infected patients, though the difference was not statistically significant ($X^2 = 1.792$, df = 1, p = 0.180)

Out of the total 88 patients in the study group, 69 (78.40%) had the desired treatment outcome (either cured or completed). Of the remaining 19 patients, 3 (3.4%) were treatment failure, 2 (2.27%) were transferred out, 8 (9.10%) were shifted to MDR therapy and 6 (6.81) died during the treatment. There were no defaulters in the study group.

The success rate of DOTS regimen was 78.40% in study group and 91.12% in control group. There was a statistically significant difference in the treatment outcome of Tuberculosis patients in both the groups. In other words, treatment outcome of tuberculosis patients on DOTS regimen depends on the HIV status of the patient.

Amongst those patients in category I, desired outcome was seen in 54 (80.6%) patients and in category II, desired outcome was seen in 15 (71.42%) patients. However, no significant statistical difference was found in treatment outcome of new and previously treated patients in HIV-TB co-infection.

There were 69 (38.76%) patients in the present study who had positive pre treatment sputum smear. Of these, 57 (78.26%) were declared either cured or completed treatment. Among 109 (61.24%) patients who were sputum negative, 94 (86.20%) completed their treatment. Though treatment success rate was higher in sputum smear negative TB patients, it was not statistically significant.

Out of 69 sputum smear positive patients, 52 (75.36%) belonged to category I (New smear positive) and remaining 17 (24.64%) belonged to category II.

Cure rate in new smear positive TB cases was 76.93% and in retreatment cases it was 58.83%. Treatment success rate in both the groups was 65.21% and 70.58% respectively. However there was no significant difference in the treatment outcomes of both the groups.

Table 7: Follow up of study and control group.

Symptoms	Serostatus of TB cases		P value
	Positive (n=88)(%)	Negative (n=90) (%)	
Extension of IP			
Yes	11 (12.5)	07 (7.88)	**0.296***
No	77 (87.5)	83 (92.22)	
Treatment discontinuation			
Yes	00	03 (3.33)	**0.245#**
No	88 (100)	87 (96.67)	
Weight gain (kg) (Mean ± S.D)	2.246 ± 1.147 (n=69)	3.384 ± 1.54 (n=82)	**<0.0001**

* Pearson's Chi S quare test; #Fischer's exact test; $ Independent sample t test

Out of the 69 sputum smear positive cases, 32(46.37%) were seropositive and 37(53.63%) were seronegative. The overall treatment cure rate was 72.46%. Treatment success rate among seropositive cases was 75% and among seronegative it was 89.18%. However the difference was not significant ($X^2 = 2.404$, df = 1, p = 0.120, Non-significant).

Out ofthe 88 TB-HIV co-infected patients, 53 were put on ART during the treatment course of DOTS. The treatment success in this group was 73.58% and in patients without concomitant ART was 85.72%. This fact can be misleading as patients with concomitant ART were less likely to die (5% in those without ART vs 0.00% in those with concomitant ART and AKT). However our study failed to find any significant association between treatment outcome and ART in HIV-TB co-infected patients.

Treatment outcome of tuberculosis is found to be significantly associated with basic CD4 counts at the start of AKT.

Extension of intensive phase was seen in 12.5% of study group and 7.88% of control group. There was no case of treatment discontinuation in the study group while the control group had 3 cases of treatment discontinuation. The reason for discontinuation was side effects to AKT.

Mean weight gain during the follow up period was respectively 2.24 kg (range: 1-4.5 kg) in study group and 3.384 kg (range: 1-7 kg) in control group. There was significant association between average weight gain and serostatus of the patients.

DISCUSSION

Demographic profile:

Mean age of seropositive TB patients was 38.42 years (standard deviation: 9.48, range: 18-65 years) while it was 33.96 years for seronegative TB patients (standard deviation: 13.64 years, range: 16-75 years). Male to female ratio was on higher side in seropositive patients (2:1 to 1:2) as compared to control group. Majority of patients were Muslims (52.80%) in our study. As per the education status, 55.67% (49) of the patients in the study group and 85.56% (77) of the patients in the control group had studied only up to Secondary School or below.

These findings are similar to study done by Shastri [4] Tripathi S et al [5], Patil et al [6] Kamath, et al [7].

According to our study, Fever and Cough, were the most common symptoms observed in both the study and the control group. Examination findings revealed pallor, lymphadenopathy especially cervical lymph nodes and Respiratory system findings like presence of crepts, rhonchi and diminished air entry

These findings were similar to study done by Kumar P et al [8] Ahmad Z et al [9] Gagiya et al [10].

Out of 88 HIV-TB co-infected patients, 10 (11.36%) had a past history of Tuberculosis. While 27 (30%) of seronegative patients had past history of Tuberculosis.

Of the 10 patients of the study group who had past history of TB, 9 (90%) had suffered from pulmonary disease while one had history of extrapulmonary TB. In control group, 23 (88.46) patients had pulmonary TB and 3 (11.54%) had extrapulmonary TB.

In both the groups, the predominant type of Tuberculosis was Pulmonary (55.68% in study group and 73.33% in control group). Majority of patients in both the groups were started on Cat I. Similar to study done by Shastri et al [4], Sharma et al [11].

In the study group, 69 (78.40%) patients had the desired treatment outcome (either cured or completed). Of the remaining 19 patients, 3 (3.4%) were treatment failure, 2 (2.27%) were transferred out, 8 (9.10%) were shifted to MDR therapy and 6 (6.81) died during the treatment. There were no defaulters in the study group. Similar to study done by Shastri et al [4], Chennaveerappa P.K. et al [12].

There was a significant increase in the weight among the study subjects in our study, which is comparable to the study done by Vasantha et. al [14].

Treatment outcome was significantly favourable in HIV negative patients as compared to HIV positive patients. This suggests that the treatment outcome of tuberculosis patients on DOTS regimen depends on the HIV status of the patient.

Similar to study done by Tripathy S et al [5], Chennaveerappa P.K. et al [12], Vijay et al 2011[13].

Treatment outcome was better in patients with higher CD4 counts (>200) which was similar to

study done by Sharma et al [11], but deferred with the findings of Chamie G et al [15].

CONCLUSION

It was evident from the present study that tuberculosis was more prevalent in lower socioeconomic classes, less educated population and the economically most productive age group of the society.

Pulmonary tuberculosis still being the predominant type.

Importance of DOTS therapy was re-emphasized with higher rate of compliance and favourable treatment outcomes

Treatment outcome of tuberculosis patients on DOTS depended on the HIV status of the patient and their CD4 counts (>200) levels.

Recommendations:

The findings of the present study recommend early and aggressive case detection of cases of tuberculosis, especially those with HIV co-infection. Enhanced supervision with adequate monitoring and follow up of treatment outcomes among all TB patients to reduce default.

Efforts need to be directed to increase awareness about the disease in the general population, especially those from lower socioeconomic strata and lower education level.

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