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Original Research Article

Impact of human immunodeficiency virus on category I pulmonary tuberculosis cases in a tertiary care hospital: a case control study

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ABSTRACT

Background: Tuberculosis (TB) is an opportunistic infection (OI). OIs are infections that occur more often or are more severe in people with weakened immune systems than in people with healthy immune systems. Human immunodeficiency virus (HIV) weakens the immune system, increasing the risk of TB in people with HIV. This case control study was done to assess the impact of HIV on clinical aspects and treatment outcome of newly diagnosed bacteriologically positive pulmonary tuberculosis.
Methods: This study was done among unmatched 75 cases and 75 controls who were pulmonary TB and TBHIV co-infected patients. Data were collected using a pretested, structured, interviewer-administered questionnaire and was analyzed using descriptive and analytical statistics.
Results: Total 150 patients were enrolled in the study out of which 75 patients had HIV-TB co-infection while remaining 75 patients were diagnosed as pulmonary TB. Treatment success rates are 74.7 % (56/75) for TB-HIV co-infected patients and 82.7% (62/75) for pulmonary TB patients. TB-HIV co-infected patients had a higher risk of an unsuccessful treatment outcome [(p = 0.232) with OR and 95% CI of 0.68 (0.28-1.36)]. The risk of unsuccessful treatment outcome was associated with family history of TB, Tobacco use, low BMI.
Conclusions: TB treatment success rate is good as compared to the WHO minimum requirement. Successful treatment outcome is lower among patients with HIV infection, tobacco use, low BMI, <200 /mm^3 CD4 count patients. Therefore, due emphasis should be given to these high-risk groups.

Keywords: HIV-AIDS, Treatment outcome, Tuberculosis

INTRODUCTION

Tuberculosis (TB) is a communicable disease, one of the top 10 causes of death worldwide and the leading cause of death from a single infectious agent. About one-quarter of the world's population has TB infection. Worldwide every year, 10 million fall ill with TB while 1.5 million die because of this preventable and curable disease making it world's top infectious killer. Most of the cases come from low and middle income countries.[1,2]

According to the Global TB report 2021, geographically, in 2020, most TB cases were in the WHO regions of South-East Asia (43%), Africa (25%) and the Western Pacific (18%), with smaller shares in the Eastern Mediterranean (8.3%), the Americas (3.0%) and Europe (2.3%). Among all incident cases of TB, 8% were people living with HIV. Even with low prevalence, India has the

second highest HIV burden globally with an estimated 23.19 lakh PLHIV in 2020.

Those with compromised immune systems, such as people living with HIV, malnutrition or diabetes, or people who use tobacco, have a higher risk[1]. HIV TB co-infection has emerged as a "deadly syndemic". HIV-associated TB contributes substantially to the burden of TB-associated morbidity and mortality. TB remains the leading cause of death among people living with HIV, accounting for around one in three AIDS-related deaths.

In 2020-2021, COVID-19 pandemic was a setback to fight against TB which is one of the reasons for decreased notification of TB related cases and deaths. India TB report 2022 has reported a jump of 11 percent in TB related cases and 13 percent rise in TB related deaths compared to that of previous year suggesting the pandemic situation under control. The prevalence rate of all form of TB was 312 per one lakh population. Malnutrition, HIV, diabetes, alcohol and tobacco smoking are the co-morbidities that impact person suffering from TB. In 2020, the cure rate of the notified TB patients was reported to be 83 percent.

The HIV positive TB incidence in the country is about 3.8 percent. People living with PLHIV are 29 times (26-31) more likely to develop tuberculosis disease than people without PLHIV and living in the same country. TB is a leading cause of hospitalization and death among adults and children living with HIV, accounting for one in five HIV-related deaths globally.

Maharashtra has the highest estimated number of PLHIV (3.30 Lakhs, 2.53- 4.35) followed by Andhra Pradesh (2.70 Lakh, 2.00-3.58), Karnataka (2.47 Lakh, 1.91-3.23).

Tuberculosis and HIV co-infection is associated with significantly increased likelihood of mortality resulting in significantly lower treatment success rates compared to non-HIV infected TB patients.[8] There is paucity of data from India on the impact of HIV related immunosuppression on response to TB treatment and subsequent mortality. With the above background, the present study was therefore proposed to study the impact and treatment outcome of HIV on category I drug sensitive newly diagnosed sputum smear positive pulmonary tuberculosis and its comparison with those without HIV in a tertiary care hospital.

METHODS

A case control study was conducted on 75 cases who were TB-HIV co-infected patients and 75 controls who had drug sensitive category I newly diagnosed sputum positive patients in a tertiary medical college. Study population includes diagnosed cases of category I new sputum smear positive pulmonary TB cases with HIV and without HIV. Patients below 18 years, previous history of TB and with co-morbities like diabetes, hypertension were excluded from the study. Universal sampling method was used until the desired sample size was achieved. An interview based pre-tested and validated questionnaire was developed under expert guidance. This was used as a data collection tool. The questionnaire contained information regarding following aspects: sociodemographic factors, clinical profile and records, investigation and clinical examination.

Written informed consent was sought from the study participants. Patients registered during the initial phase were followed up for a period of 6 months. Three follow up visits were done during the period, preferably at time of scheduled sputum examination. Basic parameters used for follow up were: clinical improvement and sputum conversion. During this phase, each interaction with the patient was used as an opportunity to educate the patient and his/her relatives. Patients and their relatives were educated about importance of proper nutrition, hygiene, control and prevention of TB and diabetes with special emphasis on adherence to treatment. During follow up phase, if clinical condition of the patient deteriorated, he/she was advised to visit the DOTS center or nearest health services. Institutional ethical committee (IEC) and Mumbai Districts AIDS Control Society (MDACS) approval was obtained before the start of the study.

Mean and standard deviation were calculated for all normally distributed quantitative variables. Shapiro-Wilk procedure was used to assess normality of data. Appropriate statistical tests were applied to test the association between the variables. SPSS 27.0 was used for coding and analysing the data. The mathematical modelling was done using STATA 13.1.

RESULTS

Demographic characteristics of cases and controls

Total of 150 patients were enrolled, 75 of cases and controls each. In this study, males dominated in both cases (66.7%) and controls (62.7%) groups. The mean age group in cases and controls was 41.9 years and 39.2 years respectively. The demographic details of study participants are summarized in Table 1.

Clinical characteristics of TB-HIV (cases) and TB (controls) patients

The clinical signs and symptoms in cases and controls are describes in the following table. In the study participants, cough was the most common symptom followed by weight loss, fever and hemoptysis. Pallor was also present in the patients. Hemoptysis, pallor, nausea and BMI showed statistical significance.

The mean CD 4 count in favourable outcome group was 205 cells/mm3 while in unfavourable outcome group it was 186 cells/mm3. The association of treatment outcome and CD4 count was tested by applying unpaired t test.

The t value was 0.445 at 73 degree of freedom and was not statistically significant (p=0.657) (Table 2).

Table 1: Demographic characteristics of TB-HIV (cases) and TB (controls) patients.

Variable	Category	Frequency	OR (CI) (95%)	P value
Gender				
Cases	Male	50 (66.7)	1.19 (0.609-2.329) χ^2= 0.263	0.608
	Female	25 (33.3)		
Controls	Male	47 (62.7)		
	Female	28 (37.3)		
Marital status				
Cases	Married	61(81.3)	χ^2= 2.309	0.315
	Single/ widowed	14 (18.7)		
Controls	Married	65 (86.7)		
	Single/ widowed	10 (13.3)		
Socioeconomic class				
Cases	Upper middle and lower middle	13 (17.3)	OR= 0.474 (0.219-1.027) χ^2= 3.655	0.05
	Upper middle and lower middle	23 (30.7)		
Controls	Upper lower and lower	62 (82.7)		
	Upper lower and lower	52 (69.3)		
Tobacco use				
Cases	Current	22 (29.3)	χ^2= 8.178	0.017
	Ex	13 (17.3)		
	Never	40 (53.4)		
Controls	Current	17 (22.7)		
	Ex	8 (10.7)		
	Never	50 (66.6)		
Form of tobacco				
Cases	Smoking	8 (10.7)	χ^2= 2.846	0.241
	Smokeless	27 (36)		
	Never	40 (53.3)		
Controls	Smoking	5 (6.7)		
	Smokeless	20 (26.7)		
	Never	50 (66.6)		
Alcohol				
Cases	Current	10 (13.3)	χ^2= 0.678	0.712
	Ex	9 (12)		
Controls	Never	56 (74.7)		
	Current	9 (12)		
	Ex	6(8)		
	Never	60 (80)		
Family history of TB				
Cases	Yes	9 (10.7)	0.308 (0.132-0.723) χ^2= 7.786	0.005
	No	66 (89.3)		
Controls	Yes	23 (30.7)		
	No	52 (69.3)		

Table 2: Clinical characteristics of TB-HIV (cases) and TB (controls) patients.

Variable	Category	Frequency	OR (CI) (95%)	P value
Cough				
Cases	Yes	67 (89.3)	1.28 (0.479-3.469) χ^2= 0.253	0.61
	No	8 (10.7)		
Controls	Yes	65 (86.7)		
	No	10 (13.3)		
Duration of cough				

Continued.

Variable	Category	Frequency	OR (CI) (95%)	P value
Cases	< 2 weeks	49 (65.3)	χ^2 = 0.498	0.78
	≥ 2 weeks	18 (24)		
	No	8 (10.7)		
Controls	< 2 weeks	45 (60)		
	≥ 2 weeks	20 (26.7)		
	No	10 (13.3)		
Fever				
Cases	Yes	53 (70.7)	1 (0.49-2.02)	1
	No	22 (29.3)		
Controls	Yes	53 (70.7)		
	No	22 (29.3)		
Weight Loss				
Cases	Yes	63 (84)	0.902 (0.371-2.195) χ^2 = 0.051	0.82
	No	12 (16)		
Controls	Yes	64 (85.3)		
	No	11 (14.7)		
Hemoptysis				
Cases	Yes	12 (16)	0.405 (0.185-0.888) χ^2=5.26	0.02
	No	63 (84)		
Controls	Yes	24 (32)		
	No	51 (68)		
Pallor				
Cases	Yes	44 (58.7)	2.129 (1.110-4.085) χ^2 = 5.228	0.02
	No	31 (41.3)		
Controls	Yes	30 (40)		
	No	45 (60)		
Nausea				
Cases	Yes	47 (62.7)	1.918 (1-3.681) χ^2 = 3.874	0.04
	No	28 (37.3)		
Controls	Yes	35 (46.7)		
	No	40 (53.3)		
Epigastric pain				
Cases	Yes	40 (53.3)	1.813 (0.947 – 3.471) χ^2 = 3.247	0.07
	No	35 (46.7)		
Controls	Yes	29 (38.7)		
	No	46 (61.3)		
BMI				
Cases	Normal	21 (28)	0.495 (0.251 – 0.977) χ^2 = 4.167	0.04
	Underweight	54 (72)		
Controls	Normal	33 (44)		
	Underweight	42 (56)		

Table 3: Sputum examination findings TB-HIV (cases) and TB (controls) patients.

Variable	Category	Frequency	OR (CI) (95%)	P value
ZN sputum staining				
Cases	Scanty	0	-	0.005
	1 +	61 (81.3)		
	2+	13 (17.3)		
	3+	01 (1.3)		
Controls	Scanty	05 (6.7)		
	1 +	51 (68)		
	2+	15 (20)		
	3+	04 (5.3)		

Continued.

Variable	Category	Frequency	OR (CI) (95%)	P value
First follow-up sputum examination				
Cases	Positive	17 (22.7)	1.398 (0.624 – 3.13) χ^2 = 0.667	0.41
	Negative	58 (77.3)		
Controls	Positive	13 (17.3)		
	Negative	62 (82.7)		
Second follow-up sputum examination				
Cases	Positive	16 (21.3)	2.271 (0.907 – 5.688) χ^2 = 3.175	0.07
	Negative	59 (78.7)		
Controls	Positive	8 (10.7)		
	Negative	67 (89.3)		
Third follow-up sputum examination				
Cases	Positive	14 (18.7)	2.639 (0.955 – 7.294) χ^2 = 3.692	0.05
	Negative	61 (81.3)		
Controls	Positive	6 (8)		
	Negative	69 (92)		

Table 4: Factors associated with category I new sputum positive pulmonary tuberculosis patients with HIV.

Variables		OR	95% CI	p value
Family history of TB		0.28	0.09-0.82	0.02
Tobacco use	Ex	0.71	0.17-2.92	0.63
	Never	0.69	0.26-1.82	0.45
Hemoptysis		0.26	0.098-0.717	0.009
ZN sputum examination	Scanty	11	-	-
	1+	5.27	0.45-60.72	0.182
	2+	3.26	0.24-43.08	0.36
	3+	1	-	-
Pallor		2.30	0.94-5.63	0.06
Second follow up sputum examination		1.99	0.067-59.09	0.68
Third follow up sputum examination		1.32	-	0.99
Second follow up clinical improvement		2.46	0.15-40.18	0.52
Third follow up clinical improvement		1.56	-	0.99
Adverse effect nausea		1.50	0.65-3.48	0.33
BMI		2.18	0.87-5.42	0.09
Change in weight at third follow up		0.16	0.07-0.37	0.0001
Change in TLC at third follow up		0.93	0.80-1.09	0.41
Change in SGOT at third follow up		1.01	0.98-1.01	0.94

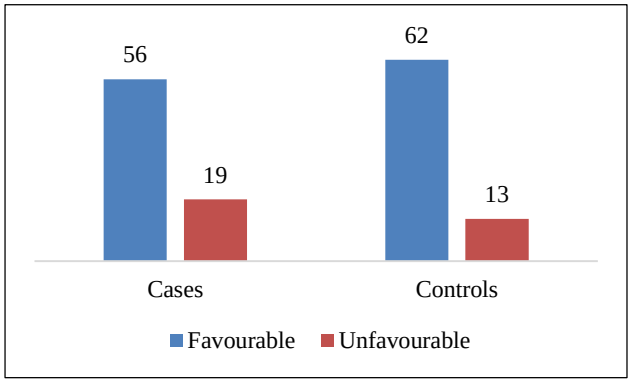

Figure 1: Treatment outcome in cases and controls.

In this study, cases with ≥200 mm^3 CD 4 count had favourable outcome compared to cases with <200 mm^3 which is similar to the other studies.

Favourable treatment outcome was observed in 56 (74.7%) cases and 62 (82.7%) controls. Unfavourable treatment outcome (failure and loss to follow up) was higher in the cases (25.3%) as compared with the control group (17.3%) (Figure 1).

To test whether the association was statistically significant or not, Pearson's Chi-square test was used. The Chi-square value worked out to be 1.43, which at 1 degree of freedom was not significant (p = 0.232) with OR and 95% CI of 0.68 (0.28-1.36).

TB treatment outcomes were better for those patients who had already initiated ART prior to their diagnosis of TB.

The variables were significantly associated in category I new sputum positive pulmonary tuberculosis patients with HIV on logistic regression analysis are family history of TB, hemoptysis, change in weight. Hosmer-Lemeshow test was used to assess model fit. The test p value was 0.3695. Both Area under curve (AUC) and Hosmer-Lemeshow test show the mathematical model used had good fit (Table 3, 4 and 5).

Table 5: Logistic regression: significant variables.

Variables	OR	95% C.I	p value
Family history of TB	0.284	0.098-0.822	0.020
Hemoptysis	0.265	0.98-0.717	0.009
Change in weight	0.166	0.073-0.378	0.001

DISCUSSION

TB is a major public health problem in the country. In this study it was observed that the maximum number of patients of HIV-TB co infection were in 31-40 years age group and pulmonary TB were in 18-30 years. Other studies have reported the number of cases are higher in 31-40 years age group.[6-9] The prevalence of HIV-TB co infection is higher among the sexually active age group. Majority of the patient of HIV-TB and pulmonary TB belonged to lower socio-economic class. Pulmonary TB disease is common in lower socio economic status.

In this study use of smokeless tobacco compared to smoking tobacco was higher among both the groups of HIV-TB co infected and pulmonary TB patients. The use of smokeless tobacco is higher as patients have perception that smoking causes respiratory illness while smokeless tobacco are associated with oral cancers. Similar results were obtained in a study by Deepak et al on prevalence of smokeless tobacco and smokeless tobacco.[9] Mariappan et al in the study on smoked and smokeless tobacco use among pulmonary tuberculosis patients (n=235) in Puducherry found 55 (23.4%) patients smoking and 23 (9.8%) using smokeless tobacco at the time of diagnosis.[10] The smoking cessation should focus on halting use of all types of tobacco.

The positive family history of pulmonary TB was significantly higher in pulmonary TB patients. This can be explained my factors like overcrowding, nutrition, poor adherence to the treatment, necessary precautions were not taken by the family contacts. Takhar et al in the study on impact of HIV co-infection on clinical presentation in patients with TB found that 27.3% of HIV-TB co-infected patients had a positive contact history with TB patient which was statistically significant (p=0.029).[12] The immunity HIV infected patient is comprised and is at risk of opportunistic infection.

In the clinical presentation, cough, weight loss, fever and hemoptysis are the classical presentation of TB in which cough for the most common symptoms and majority of them had cough for less than two weeks. Hence, highlights the improved health seeking behavior of the patients which led to early diagnosis and treatment of TB. Most of the studies show cough as the most common symptom among pulmonary TB and HIV-TB coinfected patients.[12,13] Hemoptysis was seen only in 16 % of cases. Thus, classical presenting features like hemoptysis may be absent/fewer in TB patients with HIV co-infection.

The method of ZN staining is the gold standard technique for detection of pulmonary TB. The use of the fluorescent auramine rhodamine stain which is known to be more sensitive than the Ziehl-Neelsen stain in sputum smear reading for acid fast bacilli.

Pallor was common among HIV-TB coinfected patients. The ART drugs are known to cause pallor and can be replaced with the appropriate drugs. Swarooprani et al in their study on HIV-TB co infection mentioned 52% of co infected patients having pallor.[14]

Sputum conversion is a way to monitor the treatment results in the sputum smear positive TB patients. The study participates were followed up at 2 months, 4 months and 6 months for sputum conversion and clinical improvement. The sputum conversion was lower in HIV TB patients than that of TB.[16,17] The rate of sputum conversion in HIV-TB patients depends on age, CD 4 count, extent of lung involvement, treatment adherence. The clinical improvement was better in the pulmonary TB patients than HIV-TB patients. Literature suggests patients with higher bacillary load, bilateral radiologic lesions show delayed smear conversion time and clinical improvement compared to patients with 1+ smear.[15]

The most common adverse effect reported was nausea. The ART drugs are known to cause gastro intestinal side effects. Similar results have been reported by study in South India.[12,18] The adverse effects should be dealt immediately as they may cause discontinuation of treatment leading to threat for relapse and drug resistance TB. Most of the adverse effects can be managed on an outpatient basis through a community-based treatment program.

Many of the HIV-TB coinfected patients were found to be underweight compared to pulmonary TB group. Weight loss and malnutrition are frequently described as clinical markers for poor prognosis among HIV infected patients. Multiple studies report the co relation of underweight and poor prognosis among HIV-TB coinfected patients.[12,19] Though measures like supplementary nutrition and direct benefit transfer in the patient accounts are being undertaken stringent follow up of these patients can improve the weight gain in these patients.

In this study, cases with ≥200 mm^3 CD 4 count had favourable outcome compared to cases with <200 mm^3 which is similar to the other studies.[20,21] CD4 count of <200/mm^3 indicating progressive immunodeficiency and play a major role in limiting the severity of TB.

The baseline blood investigation of patients were compared with the follow up visits for all patients. The improvement in total leucocyte count, SGOT level, creatinine levels were marginal in HIV TB co infected patients than pulmonary TB patients. This can be attributed to the fact that ATT and ART drugs (Efavirenz and Nevirapine) are known to cause hepatotoxicity.[22,23] Mo et al conducted a study on prevalence, drug-induced hepatotoxicity, and mortality among patients multi-infected with HIV, tuberculosis, and hepatitis virus. The incidence of abnormal LFT was reported more in HIVTB (11.1%) than PTB (8.3%) patients which was statistically significant with p<0.001.[24]

Treatment outcome- In this study the favourable treatment outcome was observed higher in pulmonary TB patients while unfavourable treatment outcome (failure and loss to follow up) was higher in the cases. Studies by Shastri et al and Sophie et al also state that the favourable treatment outcome ae higher among pulmonary TB group compared to TB associated with co-morbidities.[24,25]

This study has some limitations. The present study being a hospital-based study, generalizability of the study findings could be one of the concerns.

CONCLUSION

Health care providers should track HIV patients with higher risk of TB, identified on the basis of risk factors like BMI. HIV treatment compliance, CD 4 count and presence of opportunistic infections. Patients with low BMI should be closely monitored in HIV TB co infected and PTB patients. Corrective measures could be applied earlier. Regularity of treatment needs to be drastically improved in patients of tuberculosis. Stringent follow up should be done for patients whose sputum smear stays positive at two months.

Recommendations

This suggests that more tobacco and TB specific cessation messages need to be given to these patients. This is important because those who continue to smoke are more likely to have a relapse of the disease and those who relapse are more likely to develop multidrug resistant TB. Our study confirmed that most doctors' messages are general in nature, and even when addressing patients with TB tend to focus on quitting or reducing tobacco use during the illness and while taking treatment. Messages do not emphasize the necessity of quitting tobacco for good and educating patients about the higher chances of relapse of TB, if they resume use of tobacco after treatment has been completed.

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