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Original Research Article

PROPORTION OF TUBERCULOSIS AMONG PEOPLE LIVING WITH HIV WHO RECEIVED ISONIAZID PREVENTION THERAPY

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ABSTRACT

Background: In India, tuberculosis (TB) stands out as the most prevalent opportunistic infection among people living with HIV (PLHIVs) with the incidence of between 2.2 and 3.3 cases per 100 person-year. Isoniazid preventive therapy has been recommended for routine care of people living with HIV (PLHIV) to reduce the incidence of tuberculosis in PLHIVs. **Materials and Methods:** A cross-sectional study was conducted to determine the proportion of tuberculosis and the association between TB and CD4 count among eighty two (82) PLHIVs recruited through consecutive sampling, who received Isoniazid Preventive Therapy (IPT) for 6 months. Socio-demographic characteristics were taken as the independent variables. Outcome variables were TB infection confirmed by chest X-ray, sputum microscopy, Gene Xpert or culture during the study period and CD4 count by automated analyzer, Fluorescence Activated single cell sorting (FACS). The collected data were entered and analyzed in SPSS (IBM) version 26. **Result:** At the end of the study only 6% (5 patients) among 82 PLHIV under IPT developed active tuberculosis. Most of the patients were in WHO stage 1 (67.1%). Only 4.9% were in WHO stage 3 (P value of 0.006). The mean value of CD4 count among PLHIV receiving IPT having tuberculosis was significantly lower than PLHIV receiving IPT but not having tuberculosis (P value of 0.001). **Conclusion:** Isoniazid prophylaxis therapy in the dose of 300mg for six months is effective in the prevention of active TB in HIV infected patients.

INTRODUCTION

People living with HIV(PLHIV) have an increased lifetime risk of acquiring opportunistic infections and among which tuberculosis (TB) remains the most common cause of morbidity and mortality in PLHIV. According to the World Health Organization (WHO) 2017 report, there were 10.4 million incident cases of tuberculosis of which approximately 1.04 million (10%) occurred in HIV-positive patients, resulting in 374,000 TB-related deaths among people living with HIV (PLHIVs). Risk of having active TB in people living with HIV (PLHIV) is 21 times more compared to people without HIV. HIV patient who is having low CD4 count they are more vulnerable to develop active TB.[1,2]

In 2011, globally there were 34 million HIV infected patients and at least one-third of these had latent TB and 1.1 million of them developed new TB infection.[3] India bore a significant burden, contributing to 26% of the combined total of TB-related deaths in both HIV-negative and HIV-positive individuals.[4] The incidence of TB in this population varies between 2.2 and 3.3 cases per 100 person-years.[5] HIV infection weakens the immune system, rendering individuals more susceptible to Mycobacterium tuberculosis infection.[6] This increased vulnerability can result in the transition from latent tuberculosis (TB) infection to active TB disease. When exposed to stoichiometric amounts of manganese (III)-pyrophosphate, isoniazid (INH), an essential anti-tuberculosis medication, undergoes rapid oxidation. When the nicotinamide coenzyme is

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present, the oxidation of INH leads to the formation of INH-NAD(H) adducts. These adducts can act as competitive inhibitors of the enoyl-acyl carrier protein reductase InhA, which is a target for INH in the biosynthetic pathway for mycolic acids. Manganese (III)-pyrophosphate serves as an effective substitute oxidant, emulating the function of the Mycobacterium tuberculosis KatG catalase-peroxidase.[7]

Isoniazid preventive therapy (IPT) was introduce in India by NACO for the prevention of tuberculosis in PLHIV on World AIDS Day in 2016. Since then it has been used for routine care of people living with HIV (PLHIV) to reduce the incidence of active tuberculosis in PLHIV by ensuring its integration into the national HIV/AIDS program. However side effects associated with isoniazid (INH) such as abdominal pain, vomiting, skin rash, jaundice and painful neuropathy frequently leads to drug withdrawal. Polyneuropathy (PN) is a prevalent neurological complication in individuals with HIV infection. It may arise either directly due to the disease process of HIV infection or as a toxic effect associated with antiretroviral therapy (ART) other than INH.[8] Another area of concern in INH prevention therapy is development of drug resistance. However researchers found no increase in the incidence of drug resistant TB with INH prevention therapy.

Isoniazid (INH) can lead to idiosyncratic reactions, such as INH-induced lupus erythematosus, rheumatic-like syndromes, and various hematologic disorders. which tend to resolve with prompt withdrawal of the drug. Additionally, hypersensitivity reactions to INH may manifest as hepatitis, dermatitis, fever, angiitis, and hemolytic anaemia.[8]

Despite constituting only 0.2% of India's population, Manipur contributes nearly 8% of India's total HIV-positive cases.[1] The HIV prevalence rate among pregnant women attending antenatal care (ANC) in Manipur was reported to be 1.4% during sentinel surveillance in 2006.This study was undertaken to determine the prevalence of tuberculosis among people living with HIV who received Isoniazid Preventive Therapy (IPT) in Manipur, a far north eastern state of India.

MATERIALS AND METHODS

A hospital based cross-sectional study was conducted in the Centre of Excellence (CoE)ART Centre, Department of Medicine, Regional Institute of Medical Sciences, Imphal from October 2023 to March 2025. The study included eighty two (82) HIV positive patients through convenient sampling technique who are more than or equal to 18 years of age and receiving six months course of isoniazid preventive therapy (IPT). The study aimed to determine the proportion of tuberculosis among people living with HIV who received Isoniazid Preventive Therapy (IPT) and to assess the association between TB and CD4 count. Terminally ill patients, patients with active tuberculosis, any co-morbid condition such as liver failure, renal failure, sepsis, malignancy, pregnancy and patients who refused to give consent were excluded from the study. The sample size, N= 82 was calculated according to the formula, N = 1.962PQ/L2 taking prevalence of TB among IPT users of PLHIV as 8% (Mebratu W et al).[9] Socio-demographic characteristics like age, sex, religion, occupation, smoking, alcohol, ART drug history, etc. were taken as independent variables. Outcome variables were TB infection as confirmed by chest X-ray, sputum microscopy, Gene Xpert or culture during the study period. CD4 count of PLHIV on ART who received IPT (as per NACO guideline) were measured by automated analyzer, Fluorescence Activated Single Cell Sorting (FACS) machine. Isoniazid Preventive Therapy (IPT) was done by administration of Isoniazid (INH) 300mg tablet along with vitamin B6 tablet daily for a period of six months to individuals with latent TB infection and patients with no symptoms of active TB (cough, fever, night sweats, weight loss).[10] Ethical approval was obtained from the Research Ethics Board, RIMS, Imphal before commencement of the study. An informed consent was obtained from each participant before enrolling them in the study. A detailed clinical history, clinical examination and investigations reports were collected from all the participants by using a structured proforma. Detailed history regarding the signs and symptoms of tuberculosis like current cough, night sweats, weight loss, fever, etc. were obtained at the time of follow up. Participants testing positive on the symptom screening questionnaire during six months of IPT underwent chest radiography, AFB smear microscopy, GeneXpert (CBNAAT) on at least two clinical samples or culture for confirmation of suspected TB. The final diagnosis of TB in patients during or at the end of IPT was recorded in the ART center database and was extracted for analysis. Blood samples were taken to measure the CD 4 count and HIV viral loads. Collected data were checked for completeness and recorded in their proforma. The collected data were analyzed in SPSS (IBM) version 26. Summarizations of data like age, sex, education level, etc. were carried out by using descriptive statistics such as mean, standard deviation and percentages. Chi-square test and Fisher's exact test were employed to test the association between TB proportions and variables of interest like age, gender, WHO stage, etc. To determine the association between mean value of CD4 count and TB proportion independent-t test were used. P-value of less than 0.05 was taken as statistically significant.

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RESULTS

Among eighty two (82) PLHIV patients on IPT visiting the CoE ART centre, 59% (48) were female and remaining were males (41%). Maximum numbers of participants were in the age group 41 – 50 years with 41.5% followed by 51 – 60 years (28.0%) and minimum in above 70 years (1.2%). The mean age of the patients was 47.24 ± 10.81 years. Maximum of the patient had their education level at 10th pass (42.6%) followed by graduate (31.7%). Only 8.5% were illiterate. Most of the patients were in WHO stage 1 (67.1%), 23 patients (28%) were in stage 2 and only 4.9% were in WHO stage 3. The mean weight of the study population was 53.45 ± 8.42 kg and the mean CD4 count was 466.61 ± 239.63cells/cu mm. In our study only 10% (8) of the patients were diabetic and only one patient was hypertensive. At the end of the study only 6 % (5patients) among 82 PLHIV under IPT developed active tuberculosis. Tuberculosis was well distributed among the gender. Among the five tuberculosis patients, two (2) were male and three (3) were females. There was no significant association between gender and tuberculosis among PLHIV receiving IPT (P value = 0.661). There was no significant difference in mean age among PLHIV receiving IPT having tuberculosis (mean age= 45.6 years, standard deviation= 8.7) and PLHIV receiving IPT not having tuberculosis (mean age= 47.3 years, standard deviation = 10.9) where P value was 0.728.

Table 1: Association between biochemical test parameters and tuberculosis (N=82)

Sl.no.	Biochemical parameters	Tuberculosis	Mean	Standard deviation	P value
1.	Cholesterol	Yes	165.4	66.75	0.280
		No	142.2	44.88	
2.	LDL	Yes	102.8	41.92	0.060
		No	83.9	19.77	
3.	TG	Yes	138.4	38.81	0.101
		No	120.4	22.44	
4.	Hb	Yes	10.2	2.9	0.010
		No	12.6	1.8	
5.	RBS	Yes	126.60	43.20	0.641
		No	115.4	52.3	
6.	Urea	Yes	19.8	7.12	0.510
		No	27.1	24.33	
7.	Creatinine	Yes	0.8	0.05	0.626
		No	1.0	0.89	
8.	SGOT	Yes	64.2	54.88	0.414
		No	41.8	16.77	
9.	SGPT	Yes	50.0	24.45	0.190
		No	37.7	19.84	
10.	TLC	Yes	7611.4	2416.72	0.112
		No	6358.6	1641.45	
11.	PLT	Yes	3.1	1.52	0.079
		No	2.4	0.87	

The mean value of hemoglobin was significantly lower among PLHIV receiving IPT with tuberculosis in comparison to PLHIV receiving IPT without tuberculosis (P value= 0.010). There was no significant difference in mean value of remaining parameters among PLHIV receiving IPT having tuberculosis and PLHIV receiving IPT not having tuberculosis.

Table 2: Association between WHO stage and tuberculosis (N=82)

Sl.no.	WHO stages	Tuberculosis, n(%)		P value
		Yes	No	
1.	WHO stage 1	1 (1.8)	54 (98.2)	0.006
2.	WHO stage 2	2 (8.7)	21 (91.3)	
3.	WHO stage 3	2 (50)	2 (50)	

Fifty percent of the patient in WHO stage 3 was seen suffering from tuberculosis in comparison to only 1.8% and 8.7% of patients in WHO stage 1 and WHO stage 2, respectively. The association between tuberculosis and WHO stages were found to be statistically significant.

Table 3: Association between diabetes and tuberculosis (N=82)

Sl.no.	Diabetes	Tuberculosis		P value
		Yes	No	
1.	Yes	0 (0)	8 (100)	0.590
2.	No	5 (6.8)	45 (93.2)	

There was no significant association between diabetes and tuberculosis among PLHIV receiving IPT (P value = 0.590).

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Table 4: Association between CD4 count and tuberculosis (N=82)

Sl.no.	Tuberculosis	Mean CD4 count (cells/ mm3)	Standard deviation (SD)	P value
1.	Yes	128.8	47.88	0.001
2.	No	488.5	230.41	

The mean value of CD4 count among PLHIV receiving IPT having tuberculosis (128.8 cells/ mm3) was significantly lower than PLHIV receiving IPT not having tuberculosis (488.5 cells/mm3) with a P value of 0.001.

DISCUSSION

In our study, we tried to find out the incidence of tuberculosis in HIV infected patients who are receiving IPT for a period of six months. We also tried to correlate the incidence of tuberculosis with CD4 counts. The gender distribution of the study population was female predominant with forty eight (59%) of them being females and remaining thirty four (41%) were males in a total of eighty two (82) PLHIV patients enrolled for IPT. This finding is similar to a report by Semu M et al,[3] who reported a distribution of 62.6% being females and remaining 37.4% of males in their IPT exposed study population. Similarly in a study by Assebe LF et al,[6] 61.43% of the IPT group were females and remaining 38.57% were males which is similar to this study findings. But Padmapriyadarsini C et al,[4] reported more or less equal distribution of gender among the IPT patients with 51% females and 49% males. Adepoju AV et al,[11] reported in their study for female predominance of 65.3% among their study population of PLHIV on IPT. Similar finding has been reported by Sabasaba A et al,[12] with 74.4% female predominance among their study population. Thus, among the study population of PLHIV receiving IPT, females predominated the study population which is in line to the study finding of this study.

In this study maximum of the patients were in the age group of 41 to 50 years, sharing 41.5% of the total number of patients, followed by 51 to 60 years group (28%) and 31-40 years group (13.4%). The mean age was 47.24 ± 10.81 years. The mean age of the study population were higher as compared to other studies. In our study more patients were also in the higher age group as compared to previous studies. Semu M et al,[3] reported 33.3% of their study population to be less than 30 years, 22.4% in 40-49 years and above 50 years with 12%. Assebe LF et al,[6] also reported maximum patients under 30 years (42.18%) followed by 30-39 years (36.73%). Padmapriyadarsini C et al,[8] reported the average age to be 36 years among their IPT patients which is lower in comparison to this study finding. Sabasaba A et al,[12] also reported maximum of the patients in the age group of 36 to 45 years (38.2%) with the median age of 36.8 years. Adepoju AV et al,[13] reported a mean age of 40.3 ± 3.7 years in their study population with maximum of the patient in the age group of 25 to 49 years (73.6%). The higher number of older patients in our study may be explained by the declining immune status with age as well as an increased co morbidities among ageing population.

Maximum of the patients were 10th passed followed by graduate and only 8.5% were illiterate. Thus most of the patients in this study population were educated. Semu M et al,[3] reported in their study that maximum of the patients had completed primary level of education only (40.1%) followed by secondary level (37.4%), no formal education in 19.6% and very few had tertiary level education (2.8%). Similar findings have been reported by Assebe LF et al,[6] with maximum patients had primary level education (42.2%) followed by secondary level education (29.5%), no education in 18.2% and only 9.9% with tertiary level education. Thus in comparison to other studies, this study population had more number of educated patients.

In this study, most of the patients were in WHO stage I (67.1%) followed by WHO stage II with 28% and only 4.9% were in WHO stage III. Semu M et al,[3] reported 38.5% at stage II followed by stage III (31%), stage I (28.2%) and stage IV (2.3%) among their study population. Assebe LF et al,[6] reported maximum of their study population to be in WHO stage I/II with 87% and stage III/IV in 13% which is similar to this study findings. Sabasaba A et al,[12] also reported maximum study population with WHO stage I (32.9%). Thus, most of the study population were in WHO stage I and II (a total of 95.1%) in our study which is in line with prior studies. Tuberculosis is an opportunistic infection which is more common in patients with poor immune system. Patients with WHO stage I /II disease have more effective immune system as compared to patients on stage III and IV which can explain more number of participants in stage I/II as they have higher resistance/defense against TB infection and does not develop active TB.

In this study five (6%) of the PLHIV patients under IPT for 6 months had developed tuberculosis during follow up. Assebe LF et al,[6] reported 4.4% of their IPT patients with tuberculosis in comparison to 8.5% among non IPT group. Sabasaba A et al,[12] also reported 4.3% of their study population on IPT with tuberculosis. Padmapriyadarsini C et al,[4] reported only 0.5% of their IPT patient developed tuberculosis during follow up which is very low in comparison to this study. This variation in the result may be due to the fact that response collected for IPT were self reported in this study and their adherence to it was not explored. But in a study conducted by Mebratu W et al,[9] the prevalence of TB among IPT users was 8% which is a little higher than this study finding. They also reported that the prevalence of TB among non IPT users were much

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higher with 48%. Negussie A et al,[13] also reported higher prevalence of TB among non IPT user PLHIV with 74.5% in comparison to 17.5% among IPT user PLHIV. Though our study did not included cases of TB not on IPT, other studies has found that the prevalence of TB among IPT users is comparatively lower than those among non IPT users.[9,13] It was also found that two patients which constitutes fifty percent of the patient in WHO stage 3 was seen suffering from tuberculosis in comparison to only 1.8% and 8.7% of patients in WHO stage 1 and WHO stage 2, respectively (P value 0.006). This explains the declining status of immune functions in HIV patients as the disease progresses and predisposing them to increase chances of acquiring opportunistic infections.

In this study, the mean value of hemoglobin was significantly lower among PLHIV receiving IPT with tuberculosis in comparison to PLHIV receiving IPT without tuberculosis. Anemia may be due to poor oral intake, poor nutrition, direct bone marrow suppression by the disease process itself or due to suppressed erythropoiesis in the presence of an inflammatory milieu. In this study, the mean value of CD4 count among PLHIV receiving IPT having tuberculosis was significantly lower than PLHIV receiving IPT not having tuberculosis. Thus, TB was more associated with lower CD4 count. This finding was consistent with the findings made by Assebe LF et al,[6] where they demonstrated lower CD4 count was associated with increased relative hazard for developing TB. Less than 350 CD4 cell count was demonstrated to be associated with higher incidence of tuberculosis among IPT patients.[9] A similar association between low CD4+ cell counts at ART initiation, particularly CD4+ under 200 cells/mm3, and higher risk of TB during follow-up was reported by Gupte AN et al.[14] Immune suppression has long been associated with TB and prior studies in HIV-infected individuals have shown a dose-response relationship between CD4+ cell counts, particularly at ART initiation, and risk of TB.[3,9,15] Thus this study found an association between low CD4 count and tuberculosis which is in line with finding of other studies.

CONCLUSION

Isoniazid prophylaxis therapy in the dose of 300mg is effective in the prevention of active TB in HIV infected patients. Reducing incidence of active TB in these population will significantly reduce the mortality and morbidity in them. As more patients were in WHO group I/II, the risks and benefits of early initiation of IPT needs further studies. A longer follow up may be required to study the long term benefits of IPT. TB screening may be initiated if the CD4 count is low or below 350 as lower CD4 cell count is associated with tuberculosis.

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