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A Prospective Study to Assess Tuberculosis Treatment Outcome in TB-HIV Coinfected Patients in District Tuberculosis Centre Gwalior, M. P.

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Abstract: ***Introduction: India has the highest TB burden globally, with 2.8 million new cases in 2016, of which 87, 000 (3%) had HIV coinfection. TB-HIV co-infection increases morbidity, mortality, and treatment challenges. Strengthening collaborative TB-HIV activities, early ART initiation, and preventive strategies are crucial to improving outcomes and reducing mortality. The Objective of the study is to to assess TB treatment outcome in TB-HIV coinfection patients Methodology: A Hospital Based Prospective study carried out in Coinfected patients of HIV-TB at DTC and ART centre, of Gwalior in Madhya Pradesh during the study period from 1st April 2023 – 31st march 2024. A total of 124 sample were included in the study. Results: This study, conducted on 124 individuals revealed that in majority of the participants were cured 83 (66.9%) followed by death 13 (10.5%) followed by default 12 (9.7%) followed by completed treatment 12 (9.7%) followed by failure 4 (3.2%). Conclusion: The study highlights several positive aspects of TB treatment outcomes among HIV co-infected patients, it also underscores the need for targeted interventions. Addressing the nutritional deficiencies, improving educational outreach, and tackling prevalent personal habits such as smoking and alcohol use are essential steps. Additionally, ensuring that all patients have access to timely and comprehensive healthcare can further improve treatment success and patient outcome.***

Keywords: TB-HIV co-infection, treatment outcomes, Gwalior study, socio-demographic profile, intervention strategies

1. Introduction

India has the highest tuberculosis (TB) burden in the world with an estimated 2.8 million new cases in 2016 [1]. Of these cases, 87.000 (3%) were estimated to also have human immunodeficiency virus (HIV) co-infection, which is the second highest TB-HIV burden in the world after South Africa [1]. TB infections in persons with HIV increases the risk of morbidity and mortality and is one of the strongest independent predictors of unfavourable treatment outcomes (death, lost to follow-up, treatment failure) [2] Human immunodeficiency virus (HIV) and tuberculosis (TB) are the first and second leading causes, respectively of death globally due to a single infectious agent [3]. Due to the shared immune defense mechanisms between the two diseases, TB is a leading preventable cause of death among people living with HIV and vice versa [4–6].

Since 2004, the World Health Organization (WHO) has recommended testing all TB patients for HIV to allow for early initiation of anti-retroviral therapy (ART) and cotrimoxazole preventive therapy (CPT), thereby reducing mortality [7]. Although, India was an early adopter of these guidelines, treatment success rates for TB patients with HIV remain lower than treatment success rates for TB patients without HIV [7] In 2014, the treatment success rate for TB patients with HIV was 76% compared to 87% for TB patients without HIV [8].

In addition, in 2014, patients co-infected with drug-sensitive TB and HIV in Delhi had an 11% lower treatment success rate compared to patients with drug sensitive TB alone, suggesting a need to improve TB treatment outcomes among TB-HIV co-infected patients in Delhi [9]

As evidenced by several research reports globally, susceptibility to TB increases manifold with concurrent HIV infection. HIV increases the probability of recently acquired TB infection to progress to the status of active disease [10, 11, 12] and the co-occurrence of TB is not limited to the stage of HIV. It is fast becoming evident that the TB population should be seen as an important cohort to screen for HIV. [11, 12] It has been documented that coinfection with HIV and *Mycobacterium tuberculosis* has a synergistic effect on each other, and in later stages of HIV infection, TB may present as extrapulmonary disease. [13]

2. Aims & Objectives

1) To assess TB treatment outcome in TB-HIV coinfection patients.
2) To assess prevalence of HIV among registered TB patients of Gwalior DTC.
3) To assess socio demographic profile of TB-HIV coinfected patients.
4) To suggest measures to improve utilization/compliance of antitubercular and antiretroviral drugs.
5) To suggest the recommendations as per study findings.

3. Materials and Methods

The thesis work entitled ―A Prospective Study To Assess Tuberculosis Treatment Outcome In Tb-HIV Coinfected Patients In District Tuberculosis Centre Gwalior, M. P. was carried out as below:

Place of study: The study was designed in the Department of Community Medicine/PSM, Gajra Raja Medical College,

Gwalior. It was carried out in District Tuberculosis Centre and ART Centre, Gwalior.

Period of study: From 1st April 2023 – 31st march 2024 (data would be collected from registered patient at district TB centre from 1st July 2022 to 30 June2023)

Sample size calculation: By reference document analysis, From the study of To calculate the sample size, we have taken 24.4 prevalence of Tuberculosis treatment outcome among Tuberculosis-HIV Coinfected Patients. By considering 10% absolute error and 95% confidence interval, the sample size to be taken will be N= 4PQ/L, where P= Prevalence of study=24.4%, Q = (100-P) = 0.5, L = absolute error = 10%. The calculated sample size was 124, after adding 5 percent non response it comes to be around 124.

Sample Size: The sample size has been calculated by the following steps:

$n = z^2 \times p\ q$
l^2

here, n=sample size
z= z value (i. e 1.96 for 95% confidence interval) p = prevalence
q= 100-p= 24.4%
l= margin of error (10% of prevalence) $n = (1.96)^2 \times (75.6) \times (50)$
$(7.56)^2$ Taking p=0.5 q= 0.5 l = 0.1 z = 1.96

Considering the above formula sample size calculated which came out to be 124

Ethical Consideration
Ethical clearance for the study was obtained from the Institutional Ethical Committee of Gajra Raja Medical College, Gwalior (M. P.) before starting the study.

Inclusion Criteria: All the patients registered for pulmonary or extrapulmonary TB with HIV positive status during the study period from 1st April 2023 – 31st march 2024 (data would be collected from registered patient at district TB centre from 1st July 2022 to 30 June2023)

Exclusion Criteria:
1) Patients not willing to participate in the study.
2) Patients previously diagnosed or registered as HIV positive

Pre-Testing: At the beginning of the study, the questionnaire was pretested on 20 subjects to test the feasibility, reliability & validity of the questions and to make sure that the questions don‘t hurt the sentiments of the subjects while eliciting the required information. Keeping these in mind, the questionnaire/schedule was modified, corrected & finalized for data collection.

Data Collection: Data was collected after ethical approval from Institutional Ethics Committee of G R Medical College. Prior to data collection, the respective health authorities were intimated about the purpose of the study; their permission and cooperation were sought. Informed consent was obtained from each and every study subjects telephonically and after being assured about the confidentiality of the information. A predesigned, pretested, structured interview-based questionnaire was used for data collection from all the study participants.

Data Analysis: Data collected will be entered in Microsoft excel and interpreted in SPSS software with the help of appropriate statistical tests, Percentage, Proportion, Chi square and other test would be applied.

4. Results

In the present study the Socio-demographic characteristics of the 124 respondents to the survey, the overall prevalence of HIV-TB coinfected treatment outcome in this study was cured 83 (66.9%) followed by death 13 (10.5%) followed by default 12 (9.7%) followed by completed treatment 12 (9.7%) followed by failure 4 (3.2%).

Table 1: Distribution of study participants according to their age Socio- Demographic Profile (n=124)

Variables		Frequency (n)	Percentage (%)
Age group	10-30	29	23.4
	31-50	81	64.3
	51-70	14	11.3
Gender	Male	94	75.8
	Female	30	24.2
Occupation	Agriculture	1	.8
	Unemployed	4	3.2
	Large Business/Small Business/ Private Job	8	6.5
	Student	47	37.9
	Local Transport Driver/ Laborer	26	21.0
	Household worker/ Housewife	16	12.9
	Government job/ Clerk	21	17.7
Education	Illiterate	**34**	**27.4**
	Primary School	**8**	**6.5**
	Middle School	**32**	**25.8**
	High School	**20**	**16.1**
	Intermediate	**5**	**4.0**
	Graduate/Post Graduate	**25**	**20.2**
Socio- Economic	I Upper Class	11	8.9

Status	II Upper Middle Class	30	24.2
	III Lower Middle Class	37	29.8
	IV Upper Lower Class	40	32.3
	V Lower Class	6	4.8
Religion	Hindu	121	97.6
	Muslim	3	2.4
Marital Status	Married	113	91.1
	Unmarried	8	6.5
	Divorced/ Widowed	3	2.4
Type of family	Nuclear family	120	96.8
	Joint Family/ Three Generation Family	4	3.2
Overcrowding	Present	84	67.7
	Absent	40	32.3

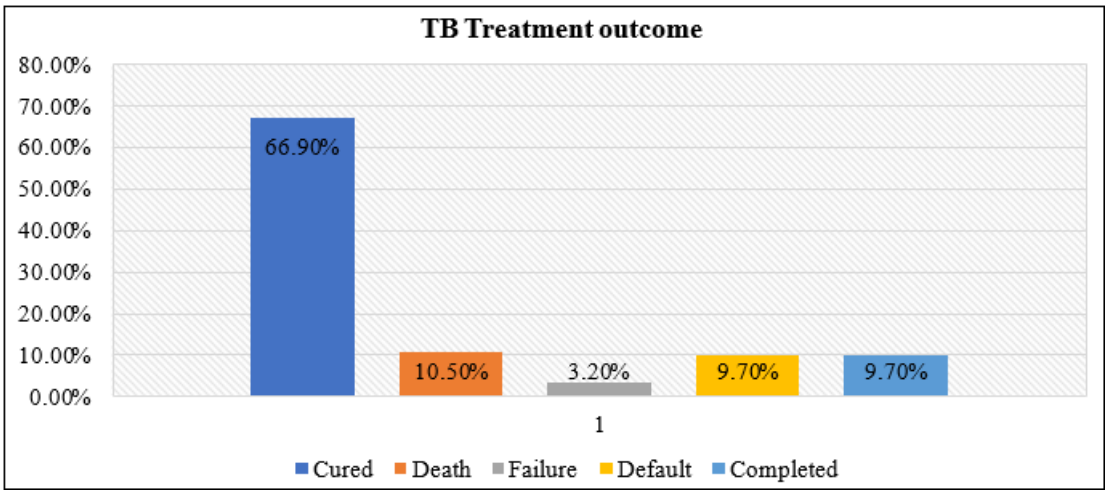

Figure 1: Distribution of study participants according to TB treatment outcome (n=124)

Table 2: Distribution of study participants according to TB Treatment Outcome in HIV-TB Coinfected Patients

Variable		Frequency (n)	Percentage (%)
BMI	<18.5 (Underweight)	50	40.3
	18.5-24.99 (Normal Range)	44	35.4
	25-29.99 (Pre Obese)	30	24.3
Nikshay Poshan Yojana	Advantage taken	124	100
Nutritional Recovery	Weight gain	75	60.5
	Weight Loss	49	39.5
Type of TB	Drug Sensitive TB	124	100.0
TB Regimen	Intensive phase (2 month)	50	40.3%
	Continuation phase (4 month)	74	59.7 %
Present HIV status and ART Regimen	On ART (TLD+DTG)	123	99.2
	Not On ART	1	.8
CPT (Cotrimoxazole preventive therapy)	Completed	113	91.1
	Not Completed	11	8.9
Comorbidity	Diabetes mellitus	5	4.0
	Hypertension	20	16.1
	No Co-Morbidity	99	79.8
Past History of TB	Yes	14	11.3
	No	110	88.7
Initial CD4 Count	Stage 1 (HIV infection): 500 cells per microliter	0	0
	Stage 2 (HIV infection): is 350 to 499.	4	3.2
	Stage 3 (advanced HIV disease or AHD): 200 to 349	54	43.5
	Stage 4 (Acquired immunodeficiency syndrome [AIDS]): less than 200	66	53.2
Smoking	Current smoker	91	73.4
	Never	26	21.0
	Past History	7	5.6
Alcohol Intake	Current	89	71.8
	Never	28	22.6
	Past History	7	5.6
Tobacco Intake	Current	92	74.2
	Never	26	21.0

	Past History	6	4.8
TB Treatment Outcome	Cured	83	66.9
	Death	13	10.5
	Failure	4	3.2
	Default	12	9.7
	Completed	12	9.7

5. Discussion

The overall prevalence of **HIV-TB coinfected treatment outcome** in this study was cured 83 (66.9%) followed by death 13 (10.5%) followed by default 12 (9.7%) followed by completed treatment 12 (9.7%) followed by failure 4 (3.2%). According to **Kumar A et al** The study reported that out of 4842 TB cases, 1068 (33.21 %) were cured, 2449 (50.58 %) completed treatment, 41 (0.85 %) were classified as treatment failures, 478 (9.87 %) resulted in TB-related deaths, 196 (4.05 %) were loss to follow up and 70 (1.45 %) cases with unassigned outcomes. Regarding treatment outcomes, 2449 cases (50.58 %) were classified as treatment completed, followed by 1068 cases (33.21 %) classified as cured. Overall treatment success rate was 83.8 %.[14] According to **Madan C et al** Of the 816 patients included in our study, 659 (81%) had favourable TB treatment outcomes (i. e., cured and treatment completed).[15]

Majority of the **Age group** is 31-50 years which is 81 (64.3%) followed by age group 10-30 years which is 29 (23.4 %) followed by 51-70 years which is 14 years (11.3%). According to **Kumar A et al** The age group of 25–54 years comprised half of the TB cases (2438 cases, 50.3 %). The highest number of TB cases were in the age group of 35–44 years, accounting for 840 cases (17.3 %), while children under 14 years made up 445 cases (9.2 %) of the total.[14] According to ***Dr Mohammed Hidayath Hussain et al*** The most common age group affected in our study was 30-39 years (48.2%) followed in order by 40-49 years (24.5%), 15-29 years (20%) and >50 years (7.3%).[16]

Majority of the participants were Males which is 94 (75.8) followed by females which is 30 (24.2%). According to **Kumar A et al** Among the analyzed records, 3066 (63.3 %) were males, 1769 (36.5 %) were females and seven (0.1 %) were transgender.[14]According to **Getie and Alemnew et al** All 270 registered tuberculosis cases of these 270 cases, 53.3% were males and 46.7 % were females.[17]

Majority of the participants were students which is 47 (37.9%) followed by Local transport drivers which is 26 (21.90%) followed by Government job/clerk which is 21 (17.70%) followed by Large Buisness/Small Buisness/ Private Job which is 8 (6.5%) followed by Unemployed which is 4 (3.2%) followed by Agriculture which is 1 (0.80%). According to **Gharat Vaibhav et al** Around 38% of the participants were labourer which includes working as labourer in diamond work, textile work, looms work and Diagnosis of both HIV and tuberculosis was positive at the same time in 104 (51.0%) of the patients.[18]

According to **Khajuria Rajesh et al** Majority of the subjects in all the three groups were housewives (22.6%) followed by businessmen (16.4%) and skilled workers.[19]

Majority of the participants were Illetrate 34 (27.40%) followed by Middle school 32 (25.8%), followed by Graduate /Post Graduate 25 (20.2%) followed by Primary school 8 (6.5%) followed by Intermediate school 5 (4%). According to **Gharat Vaibhav et al** Major portion of patients had primary 72 (36.0) and secondary 75 (37.5%) education. It was found that 22% of the HIV-TB co-infected patients were illiterate.[18] According to ***Dr Mohammed Hidayath Hussain et al*** The most common age group affected in our study was 30-39 years (48.2%) followed in order by 40-49 years (24.5%), 15-29 years (20%) and >50 years (7.3%).[16]

Majority of the participants were Upper Lower class 40 (32.3%) followed by Lower middle class 37 (29.8%) followed by Upper Middle class 30 (24.2%), Followed by Upper class 11 (8.9%) Followed by 6 (4.8%). According to ***Debahuti Sabhapandit et al*** Highest number of HIV positive cases, pulmonary TB cases and HIV-TB coinfection cases comprising of 64, 183, 9 in numbers belonged to lower class [20] According to **Khajuria Rajesh et al** the vast majority of our subjects belonged to the upper lower socioeconomic class.[19]

Majority of the participants were Hindu 121 (97.6%) followed by Muslims 3 (2.4%). **According to Meena et al** The majority (90%) of the cases in the current study were Hindus and 10% were Muslims.2[1]According to **Khajuria Rajesh et al** More than 60% of the study subjects were Hindus.[19]

Majority of the participants were Married 113 (91.1%) followed by unmarried 8 (6.5%) followed by Divorced/ Widowed 3 (2.4%). **According to Meena et al** The majority of the patients were married (70%) and 18% were widows and 12 % were umarried[21] According to ***Debahuti Sabhapandit et al*** The distribution of married and unmarried person was equal 1: 1 in the HIV-TB coinfection group[20]

Majority of the participants were from Nuclear Family 120 (96.8%), Followed by 4 (3.2%). In the study conducted by **Gurung et al [22] and T. A. Pakasi et al [23]** more than half of participants belonged to Joint family.

Majority of the participants Overcrowding were Present 84 (67.7%) followed by overcrowding is Absent in 40 (32.3%) of participants. In the study conducted by Shukla et al most of participants (52.5%) were living in Pucca house. Majority of houses (67%) were crowded and 31% of all participants were practicing open defecation.[24]

Majority of the participants were in <18.5 underweight 50 (40.3%) 18.5-24.99 Normal Range 44 (35.4%), Followed by 2529.99 Pre-obese30 (24.3%). According to **Maji Debapriya et al** BMI <18.5 kg/m2 was seen in 44 patients (83.1%).2[5]According to **Limenh Workie et al** total of 401 patients were enrolled in TB treatment in Motta Town. The

average BMI for the respondents was 18.11 with a SD of 2.51.[26]

All of the participants were getting advantage of nikshay poshan yojana 124 (100%) According *to* ***Sharma P et al***. All patients received benefit under NPY. But only 26 (13.7%) received incentive in scheduled time.[27]

Majority of the participants were gain weight 75 (60.5%) Followed by participants who had weight loss.49 (39.5%) According to **Limenh Workie et al** The nutritional assessment of the patients revealed that 61.9% of them had mild acute malnutrition [26]
All participants were having Drug sensitive TB 124 (100%)) According to **Madan C et al** Among these TB-HIV co-infected patients, 816 (88%) were included in our study as they had drug-sensitive TB.[15]

Majority of the participants Followed by continuation phase 74 (59.7%) were in intensive phase 50 (40.3%). According **Giridharan P et al** to were under first-line TB treatment for pulmonary TB (98.6%, n = 310, 813).2[8] According to **Adisa et al** out of 140 participants Fifty-one (36.4%) of the DS-TB patients were in the intensive phase of treatment, while 89 (63.6%) were in the continuous phase.[29]

Majority of the participants were on Art 123 (99.2%) followed by participants who are not on ART 1 (0.8%). According to **Maji Debapriya et al** The majority of the patients, 98.12% (n=52) were ART naïve and one patient (1.88%) was already on ART.2[5]
Majority of the participants were on Completed CPT 113 (91.1%) Followed by participants who not completed CPT 11 (8.9%) According to **Gebresillassie et al** Approximately 259 (98.10%) of the PLWHA received correct dose of CPT.[30]

Majority of the participants had no comorbidity 99 (79.8%), followed by hypertension 20 (16.1%), followed by diabetes mellitus 5 (4%) In the study of **Beatrice B. Musuenge** et al the prevalence of hypertension and diabetes was both 2%.[31] **Zekariyas Sahile et al** observed that out of 456, 23 (5.08%) and 10 (2.21%) were having hypertension and Diabetes respectively.[32]

Majority of the participants were not having Previous history of TB 110 (88.7%) followed by the partcipants who are having Previous history of TB 14 (11.3%). According to **Vega V, et al** Out of 499 records Eighty five records assessed factors associated with either recurrent TB and reinfection.[33]

Majority of the participants were having Stage 4 (Acquired immunodeficiency syndrome [AIDS]): 66 (53.2%) followed by Stage 3 (advanced HIV disease or AHD): 54 (43.5%) followed by Stage 2 (HIV infection): 4 (3.2%) followed by Stage 1 (HIV infection) 0 (0%). (Table 23) According to ***Dr Mohammed Hidayath Hussain et al*** Out of 110 patients 71 (64.5%) had CD4 count < 200 cells/µl and 39 (35.5%) had CD4 count >200 cells/µl.65 (92%) of 71 patients with CD4 count <200cells/µl and 26 (67%) of 39 patients with CD4 count > 200cells/µl presented with atypical pattern of pulmonary tuberculosis.[16] According to **Maji Debapriya et al** Seventy-one percent (71%) of them with unfavourable outcomes had a CD4 cell count of less than 100 cells/mm3. The mean CD4 count (n=46, 87%) at TB diagnosis was 190±137.03 while that at the completion of TB treatment (excluding patients with unfavourable outcome, n=7) was 277±190.1.[25]

Majority of the participants were current smokers 91 (73.4%) followed by the participants who never smoked 26 (21.0%) followed by the participants who had past history of smoking 7 (5.6%) According to **K. Endalkachew et al** In their study found that out of 302 participants current cigarette smoking was prevalent among 172 (57.0%) [34]In the study conducted by **Abdilahi Ibrahim Muse et al** out of 295 study participants, 21 (7%), 35 (12%) and 3 (1%) were currently cigarette smokers, Khat chewers and alcohol drinkers respectively.[35]

Majority of the participants were current alcoholic 89 (71.8%) followed by the participants who never take alcohol 28 (22.6%) followed by the participants who had past history of taking alcohol 7 (5.6%). In the study of **K. Endalkachew et al** out of 405, Half i. e., 216 (53.3%) of the study participants consumed alcohol.3[4] According to **Beatrice B. Musuenge et al** current alcohol consumption was found among 175 (57.9%) and former alcoholic were 103 (34.1%) [31]

Majority of the participants were current taking tobacco 92 (74.2%) followed by the participants who never take alcohol 26 (21.0%) followed by the participants who had past history of taking Tobacco 6 (4.8%). According to **Shukla et al** 162 in their study observed that nearly half of study participants were consuming tobacco or alcohol or both.[24]

6. Conclusion

The study on tuberculosis (TB) treatment outcomes among TB-HIV co-infected patients in Gwalior provides valuable insights into socio-demographic factors, nutritional status, disease characteristics, and treatment responses. The findings highlight that most patients belong to economically disadvantaged backgrounds, with a high prevalence of overcrowding and poor literacy levels, indicating the need for targeted public health interventions. Despite receiving nutritional support, many patients remain underweight, suggesting gaps in nutritional management. The study also emphasizes the importance of early HIV diagnosis and continuous antiretroviral therapy (ART) adherence. While the treatment success rate is promising at 66.9%, challenges persist due to mortality (10.5%), treatment default (9.7%), and failure (3.2%). Personal habits like smoking and alcohol consumption further complicate treatment outcomes. Strengthening healthcare accessibility, adherence support, and awareness programs can enhance treatment efficacy and patient well-being. Focused interventions addressing these challenges are crucial to improving TB-HIV co-infection management**.**

7. Recommendation

To improve TB-HIV co-infection management, targeted interventions are essential. Strengthening nutritional support through personalized assessments and dietitian involvement can help address malnutrition. Expanding health education tailored to low literacy levels and establishing patient support

groups can enhance treatment adherence and psychological well-being. Implementing robust adherence strategies, such as follow-ups and counseling, can reduce treatment default rates. Integrating substance use cessation programs into TB-HIV care is crucial for better health outcomes. Expanding diagnostic tools for early detection and ensuring accessibility can improve disease management. Lastly, increasing awareness of safe sex practices and preventive measures can help curb HIV transmission.

8. Limitations

This study's limitations include its single-center design, limiting generalizability, and reliance on self-reported data, introducing potential biases. Its observational nature restricts causal conclusions, while limited use of advanced diagnostics affects clinical assessment. Socio-economic factors require deeper exploration. Future multi-center studies with robust methodologies are needed for more comprehensive insights.

Conflicts of Interest

The authors no conflict of interest

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