Original article:

# Treatment outcome and the predictors of unfavorable outcome of Tuberculosis in HIV-TB co-infected patients in Rural Tertiary Care Centre of Western Maharashtra: A descriptive longitudinal study

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**ABSTRACT:**

Background: Patients with HIV-TB co infection are at increased risk of death, accounting for 1 in 4 AIDS related deaths. TB contributing to 20-25% of all deaths among HIV infected individuals.

Material and methods: This descriptive longitudinal study was carried out at Anti-Retroviral Therapy (ART) centre and Designated Microscopy Centre (DMC) cum Directly Observed Treatment Short Course (DOTS) centre of Pravara Rural Hospital, Loni. The ART status, CD4 and weight of the patients, type of TB, TB treatment regimen and outcome was recorded. CD4 count and weight of the patients were recorded at start, after 6 months and after 12 months follow up of ART and anti-tuberculosis treatment (ATT).

Results: Among 138 HIV-TB co-infected patients studied, favourable outcome was seen among 95 (68.84%) patients while unfavourable outcome was seen among 43 (31.15%) patients. The treatment failure rate and case fatality rate were 2.9% and 20.3%, respectively. The difference between mean CD4 count and weights of patients on ART & ATT at 6 months interval was highly significant (P value < 0.0001).

Conclusion: Presence of addictive habit, pulmonary TB and retreatment type of patient were the predictors of unfavourable outcome among co-infected patients.

Key-words: Outcome, Treatment, HIV, Tuberculosis.

**Introduction:**

Human Immunodeficiency Virus (HIV)/ Acquired Immuno-Deficiency Syndrome (AIDS) is a modern global pandemic, affecting both industrialized and developing countries. The People Living with HIV (PLHIV)are more prone to various opportunistic infections like Tuberculosis (TB), candidiasis, pneumocystis carinni, herpes zoster, herpes simplex,etc. Out of these, TB is the most common and earliest opportunistic infection among the PLHIV.

Patients with HIV-TB co infection are at increased risk of death, accounting for 1 in 4 AIDS related deaths.[1]TB contributing to 20-25%

of all deaths among HIV infected individuals.[2] There are many studies which have estimated the prevalence of TB among PLHIV but very few studies have reported treatment outcomes of tuberculosis among HIV-TB co-infected patients. The studies on treatment outcome of TB among HIV-TB co-infected patients showed unfavourable outcome in the range of 25 to 33%.[3,4] Immunosuppression in HIV positive individual which is documented by estimating CD4 cells is found to be one of the predictors of poor outcome. Deficiency of CD4 cells in HIV infected person increases the rate of both primary and reactivation of TB. Though HIV and TB can be treated simultaneously, concurrent treatment of tuberculosis and HIV is complicated by the adherence challenges, overlapping side effects of antituberculosis and antiretroviral drugs, immune reconstitution inflammatory syndrome (IRIS), drug-drug interactions.[5,6]

Most of these studies on treatment outcome are from urban setup and very few of them from rural area. HIV is spreading from urban to rural area and from individuals practicing high risk behavior to the general population. In India nearly half of the HIV-infected population live in rural areas and face a poor public health infrastructure which has management challenges and lack of funding.[7]

HIV/AIDS and TB are no longer just public health issues in India but become serious socioeconomic & developmental concerns, because both of the diseases are more prevalent in economically productive age group (15-44yrs). Deaths of young adults in productive age group have a damaging impact on their families and communities, skills are lost, work force shrinks & children are orphaned.[8]

Thus, there is a dire need to study the predictors of unfavourable outcome among the HIV-TB co-infected patients in rural set up and find out the ways to delay and prevent the morbidity and mortality related to this. Considering this we have conducted this study in Rural Medical College, Loni (RMC, Loni)

from Ahmednagar District of Maharashtra state which is one of the high HIV prevalence state in India. This study was conducted with the aim of to estimate the treatment outcome of tuberculosis and the predictors of unfavorable outcome of Tuberculosis among HIV-TB co-infected patients. This study gives us information regarding the factors responsible for unfavourable outcome in co-infected patients in rural area. This information will help in improving survival of HIV-TB co-infection patients by implementing proper interventions.

**Materials and methods:**

The descriptive longitudinal study design was used for the present study during the period of September 2014 to August 2016. This study was carried out at Anti-Retroviral Therapy (ART) centre and Designated Microscopy Centre (DMC) cum Directly Observed Treatment Short Course (DOTS) centre of Pravara Rural Hospital, Loni (PRH, Loni). This tertiary care teaching hospital runs ART and DMC cum DOTS centre which follow the guidelines of NACO (National AIDS Control Organization) and RNTCP (Revised National Tuberculosis Control Programme) respectively.

The study was initiated after prior ethical approval from Institutional ethics committee and permission from In-charge of ART and DMC cum DOTS centre. Written informed consent of the patients was taken. Confidentiality of information shared by the patients was maintained during all the stages of research. The software linked Data Collection Form was password protected so that no person other than principal investigator could access the information at any circumstances.

Primary data (Interview of patients) and Secondary data (Records of Patients) were collected for the study. As calculated sample size was more than yearly average number of patients registered at ART centre we have included reference period/Secondary data (July 2013 to August 2014) in our study. Considering the probability of favourable

outcome of TB among HIV patients as 77%,[3] the calculated sample size with allowable error of 10% was 119. With due consideration of 10% loss to follow-up, the sample size of 130 was chosen.

The treatment records of HIV positive patients from July 2013 to August 2014 registered under ART centre were included in study. For primary data patients were interviewed from September 2014 to June 2015 so that one year follow up of all the HIV-TB co-infected patients could be completed till August 2016.The records of the patients who were taking treatment in private health facility and the incomplete records were excluded from the study. During follow up, the HIV-TB co-infected patients who were transfer out, patients taking treatment at private health facility and MDR-TB patients were excluded.

A predesigned and pretested Data Collection Form was used for data collection. This Data Collection Form was prepared using Epi Info 7 new software and data was directly entered into this software linked Data Collection Form. The ART status, CD4 and weight of the patients, type of TB, TB treatment regimen and outcome was recorded. CD4 count and weight of the patients were recorded at start, after 6 months and after 12 months follow up of ART and anti-tuberculosis treatment (ATT).

Reporting: Strengthening the Reporting of Observational studies in Epidemiology i.e., STROBE which is a standard method of reporting for descriptive and analytical studies was used.
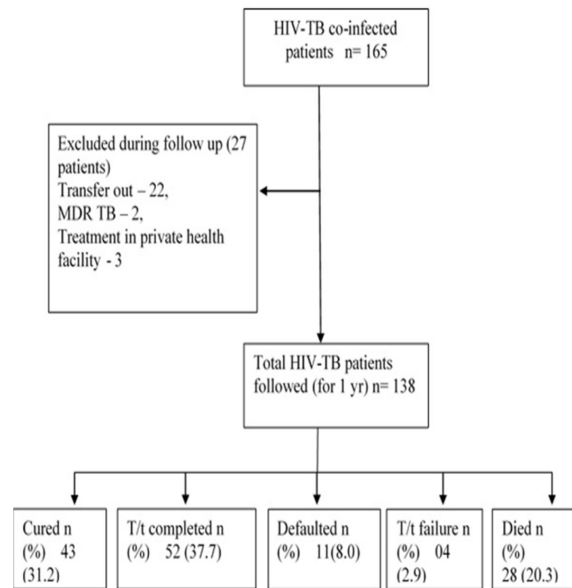
**Statistical analysis:**

Data was analysed using Epi-Info-7 New, SPSS (Statistical Package for Social Sciences) version 21 software, Graph pad and Open epi software.

**Results:**

A total of 165 HIV-TB patients were considered for follow up for treatment outcome excluding 2 MDR-TB patients.



Fig 1. Flow chart of study on treatment outcomes in HIV-TB co-infected patients

During follow up 22 patients were transfer out and 3 preferred treatments in private health facility. So, we could follow-up only 138 co-infected patients (Figure 1).

Out of 138 co-infected patients 82 (59.4%) were male, 54 (39.13%) were female and 2 (1.4%) were TG/TS. Mean age of the patients were $38.67 \pm 12.72$ years. Maximum number of patients i.e 94 (68.11%) were from rural area and 44 (31.88%) were from urban area.



Fig 2. Treatment outcomes among coinfected patients
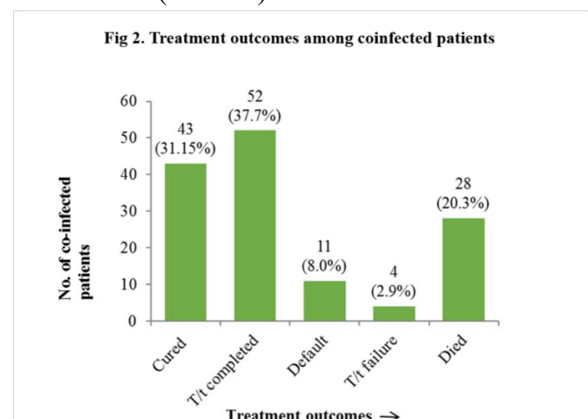
The treatment outcomes were studied in 138 HIV-TB co-infected patients as shown in Fig.2. Favourable outcome was seen among 95 (68.84%) patients which constitutes cured patients and patients who had completed the treatment. Unfavourable outcome i.e. defaulter,

treatment failure and died patients was seen among 43 (31.15%) patients.

Pulmonary type of TB was found in 102 (73.91%) patients and extrapulmonary in 36 (26.08%) patients. Among the 102 pulmonary TB patients 78 (76.47%) were sputum positive and 24 (23.52%) were sputum negative patients.



Fig 3. Treatment outcome among coinfected patients according to type of TB
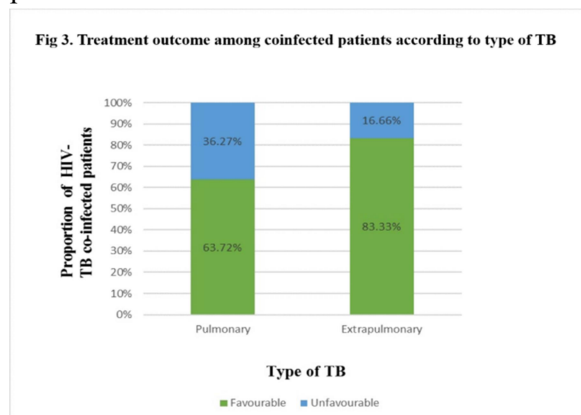
During follow up period of 1 year, total 28 patients died so CD4 and weight of the dead patients were not available and 2 patient's CD4 and weight were also not available. So CD4 count and weight of total 108 patients were studied at interval of 6 months.

Out of 165 co-infected patients, 143 (87%) patients were new type of patients with no any past history of ATT or had taken ATT for less than 1 month while 22 (13.3%) patients were previously treated. All the co-infected patients were receiving antiretroviral therapy as per the NACO guidelines. As per RNTCP guidelines, the new patients received Category I treatment, the previously treated patients received Category II treatment, and MDR TB patients received DOTS Plus treatment.

| Table 1: CD4 count and weight of co-infected patients at intervals of 6 months (n=108) | | | | | |
|---|---|---|---|---|---|
| | At start | Mean CD4 after 6 months | Mean CD4 after 1 year | Test statistic | P value |
| Mean± SD of CD4 count (cells/mm3) | 195.46±145.32 | 320.78±180.22 | 403.12±178.06 | Friedman Statistic* Fr = 149.39 | 0.0001 |
| Mean± SD weight (Kg) | 44.18±9.79 | 46.31 ±9.208 | 48.29 ±9.33 | Friedman Statistic * Fr = 86.268 | 0.0001 |
| *Test applied because the data did not pass normality test. | | | | | |

The difference between the mean CD4 count at intervals of 6 months i.e. at start of ART & ATT, 6 months after the start and then after 1 year was found highly significant (P value < 0.0001). The difference between the mean weights of the co-infected patients at intervals of 6 month was found extremely significant with P value < 0.0001 (Table 1).

**Table 2: Univariate analysis of factors associated with TB treatment outcome among co-infected patients (n= 138)**

| Variables | Unfavourable outcome (n=43) n (%) | Favourable outcome (n=95) n (%) | P value | OR (95%CI) | Power of the test (%)** |
|---|---|---|---|---|---|
| Age >40 years ≤40 years | 13(26.0) 30(34.09) | 37(74.0) 58(65.9) | 0.34 | 0.67 (0.31-1.46) | 11.61 |
| Gender Male Female | 30(36.58) 12(22.22) | 52(63.41) 42(77.77) | 0.08 | 0.49 (0.22-1.08) | 34.76 |
| Residence Rural Urban | 35(37.23) 08(18.18) | 59(62.76) 36(81.81) | 0.03 | 0.76 (0.62-0.94) | - |
| Addictive Habits Yes No | 27(42.85) 16(21.33) | 36(57.14) 59(78.66) | 0.009 | 0.36 (0.17-0.76) | - |
| Type of TB Pulmonary Extrapulmonary | 37(36.27) 06(16.66) | 65(63.72) 30(83.33) | 0.036 | 2.84 (1.08-7.47) | - |

| | | | | | |
|---|---|---|---|---|---|
| | | ) | | | |
| Sputum smear status* Smear positive Smear negative | 32(41.02) 05(20.83) | 46(58.97) 19(79.16) | 0.09 | 0.37 (0.12 - 1.11) | 33.3 8 |
| Type of the patient Retreatment New | 11(64.7) 32(26.44) | 06(35.29) 89(73.55) | 0.00 3 | 0.19 (0.06 - 0.57) | - |
| Baseline CD4 count ≤ 200 cells/mm3 >200 cells/mm3 | 25(28.73) 18(35.29) | 62(71.26) 33(64.7) | 0.45 | 0.73 (0.35– 1.54) | 8.22 |

*smear status of only pulmonary patients
**calculated only if P ≥0.05

On univariate analysis of factors associated with the treatment outcome among co-infected patients, the variables found to be statistically significant were residence (P=0.03), addictive habits (P=0.009) of the patients, type of TB (P=0.036) and type of the patient (P=0.003) (Table no. 2).

**Table 3: Multivariate analysis for predictors of unfavourable treatment outcome among co-infected patients (n= 138)**

| Factors | Unfavourable outcome (n=43) | Favourable outcome (n=95) | P value | OR (95%CI) |
|---|---|---|---|---|
| Residence Rural Urban | 35(37.23) 08(18.18) | 59(62.76) 36(81.81) | 0.06 9 | 2.44(0.93 -6.41) |
| Addictive Habits Yes No | 27(42.85) 16(21.33) | 36(57.14) 59(78.66) | 0.00 3 | 3.51(1.52 -8.11) |
| Type of TB Pulmonary Extrapulmonary | 37(36.27) 06(16.66) | 65(63.72) 30(83.33) | 0.01 7 | 3.96(1.27 -12.28) |
| Type of the patient Retreatment New | 11(64.70) 32(26.44) | 06(35.29) 89(73.55) | 0.00 1 | 8.34(2.47 -28.15) |

Table no. 3 shows Multivariate analysis for predictors of unfavourable treatment outcome among co-infected patients. The factors considered for multivariate analysis were residence, addictive habits, type of TB and type of the patient; which were found to be statistically significant in univariate analysis. It was found that presence of addictive habit [OR 3.51, CI (1.52-8.11)]; pulmonary TB [OR 3.96, CI(1.27-12.28)] and retreatment type of patient [OR 8.34, CI(2.47-28.15)] are the predictors of unfavourable outcome among co-infected patients.

**Discussion:**

HIV is a modern global pandemic, affecting both industrialized and developing countries and TB being the most common and earliest opportunistic infection among the PLHIV. Globally India ranks first in TB incidence with 2.2 million incident cases annually and ranks third in the world for HIV associated TB. Thus, India is facing dual and major public health problem of HIV and TB. HIV and TB have formed a lethal combination causing double trouble and has been described as a "cursed duet".

This study was aimed to study this cursed duet and to estimate the treatment outcome and predictors of unfavorable outcome of tuberculosis among HIV-TB co-infected patients in a rural tertiary care setup.

In this study, in favourable outcome, numbers of cured patients were 43 and numbers of patients who completed the treatment were 52. Among the patients with unfavourable outcome, 11 were treatment defaulters, 04 were treatment failure and 28 patients died. Residence, addictive habits, type of TB and type of the patients were found to be significantly associated with treatment outcome among these patients. Among these, presence of addictive habit, pulmonary TB and retreatment type of patient were the predictors of unfavourable outcome among co-infected patients.

Kamath R et al.9 and Agarwal U et al.10 observed in their studies a favourable outcome in 69.3% and 67.2% of the co-infected patients respectively, and the finding is similar to our study finding. Study conducted by Kingkaew et al.11 showed, treatment success in 493 (64%) patients. In a study by Sharma SK et al.3 the favourable outcome was observed in

332 (77%) patients. The study results of Shastri S et al. 12showed 74.5% treatment success rate.

Treatment success rate was high in 88 (85.4%) co-infected patients and the outcome was unsatisfactory (treatment failure, treatment interruption, transfer out and unknown) in 8 patients (7.8%) while 7 (6.8%) patients died in a study conducted by Fenner et al.13

Proportion of patients with default in our study (8.0%) was similar with the finding from a study by Sharma S K et. al.3, in which 8.1% co-infected patients were defaulters. A study by Kingkaew et al.11 also showed similar finding of 8% defaulters. Shastri S et al.12 observed 5.8% defaulters in their study. In a study by Ismawati et al.14, the proportion of defaulters was high i. e. 25.6%. Reason for defaulting the treatment could be initial relief from symptoms, increased pill burden, adverse drug reactions that may result from interactions between TB and HIV drugs. It could also be due to lack of awareness about the consequences of not completing the treatment, social stigma of having the disease or might be because of patients stop attending treatment centre due to ill health.

Proportion of patients with treatment failure was 1.6%, 1% and 1% in studies by Sharma SK et al.3; Kingkaew et al.11and Vijay S et al.4 respectively. Our study finding of 2.9% treatment failure rate is slightly more than these studies.

The case fatality rate of 20.3% in our study was more or less similar to 23.3% in study by Ismawati et al.14; 17.8% in a study by Agarwal U et al.10; 17.1% in a study by Kapadia J D et al.15 and 17% in a study conducted Kingkaew et al 11. In a study conducted by Kamath R et al 9, proportion of patients died was more i.e. 25%.

The proportion of patients died was lower in studies conducted by Shastri S et. al.12 (15.7%); Sharma S K et al.3 (13.2%); Karo et al.16 (10.72%) and Vijay Set al.4 (9.0%).

In our study 65 (63.72%) of the pulmonary TB patients and 30(83.3%) of extrapulmonary TB patients had favourable outcome. In a study by Sharma S K et. al. 3, among pulmonary patients, favourable outcome was observed in 75.3% patients and is higher than reported in our study (63.72%). They observed that among PTB patients, sputum positives had lower success rate compared to sputum negative group (70.9 vs 77.6%) similar to our study results of lower success rate i.e. 58.97% in sputum positive patients than 79.16% in sputum negative patients. The lower success rate among sputum positive patients might be due to default and treatment failure among them.

In a study by Vijay S et al.4, among smear positive patients the favourable outcome was observed in 62% patients and the finding is similar with our study finding.

In study conducted by Sharma S Ket al.3, favourable outcome was observed among 78% extrapulmonary TB patients and is lower than that reported in present study (83.33%).

In a study by Singhal S et al.17, 6 (43%) co-infected patients died, out of which 5 patients were with pulmonary tuberculosis and 1 extra pulmonary tuberculosis case i.e. mortality rate was high among pulmonary patients and we observed same finding in our study. But in a study by Shastri S et al.12, mortality proportions were equal in the pulmonary and extra pulmonary TB infection groups.

In our study, the difference between the mean CD4 counts at baseline, 6 months and 1 year was found highly significant (P value < 0.0001). Kumarasamy N et al.18 also showed increase in CD4 count after 6 months, after 18 months and after 24 months of initiating HAART. Kavya S et al.19 found statistically significant difference in CD4 count before and after ATT.

In a study conducted by Kamath R et al.9 significant correlation was found between CD4 rise at 6 months and initial CD4 count (P

< 0.05). Also they found significant association between rises in CD4 counts after the follow up at the sixth month (P < 0.05) on applying Wilcoxon signed rank test.

In this study, the difference between the mean weights of the co-infected patients at intervals of 6 month was found extremely significant (P value < 0.0001). Swaminathan S et al. 20 also found a significant improvement in weight, at the end of ATT. but the CD4% declined significantly.

In present study the presence of addictive habit, pulmonary TB retreatment type of patient are found to be the predictors of unfavourable outcome among co-infected patients. In a study by Vijay S et al.[23], on logistic regression analysis the factors independently associated with unfavourable outcome were pulmonary type of TB, retreatment type of patient similar to our study finding. In a study by Sharma SK et al.[16] on logistic regression analysis, the factors associated with poor outcome were $CD_4 < 200/mm^3$ and retreatment type of patient.

The limitation of the study was that it was a hospital-based study. As only patients coming to ART and DMC cum DOTS centre of RMC, Loni were included in the study, it would have introduced selection bias. Some of the important factors like drug susceptibility status and other co-morbid conditions which are likely to influence the TB treatment outcome were not studied.

Further studies are required in depth to know the causes of treatment default, treatment failure and death among HIV-TB co-infected patients.

## Conclusion:

The factors significantly associated with treatment outcome were residence, addictive habits, type of TB and type of the patient. Presence of addictive habit, pulmonary TB and retreatment type of patient are the predictors of unfavourable outcome among co-infected patients.

## Recommendations:

Addictive habits are responsible for unfavourable treatment outcome as well as death among the HIV-TB patients. So, the patients having any addictive habits should be counselled to adapt healthy behaviour and one counsellor can be posted at ART centre. They should be made aware by educating them regarding the various risks associated with it. They can be helped through deaddiction centres.

The co-infected patients from rural area are at greater risk of death so various intervention strategies should be directed to these rural people. For these patients, the facilities can be made available for stay near the ART centre. Further studies are required in depth to know the causes of treatment default, treatment failure and death among HIV-TB co-infected patients. Further studies are also required by calculating the adequate sample size for those variables which were found non significant.

## Limitations of the study:

It was a hospital based study. As only patients coming to ART and DMC cum DOTS centre of RMC, Loni were included in the study, it would have introduced selection bias. Some of the important factors like drug susceptibility status and other comorbid conditions which are likely to influence the TB treatment outcome were not studied.

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