



Original Research Article

Assessment of treatment outcome among HIV positive tuberculosis patients in Visakhapatnam

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ABSTRACT

Introduction: In March 2016, RNTCP revised its technical and operational guidelines. One of the major additions was introduction of Daily Regimen in the treatment of Drug sensitive TB, started initially among TB-HIV co-infected patients in 2017. The present study was taken up to assess the treatment outcomes of Tuberculosis among TB-HIV co-infected patients and certain factors related to the poorer outcome of the treatment.

Settings and Design: An Observational Longitudinal study, conducted at an ART centre, attached to King George Hospital in Visakhapatnam District, Andhra Pradesh, among all TB-HIV co-infected patients newly diagnosed with Drug Susceptible Tuberculosis, aged above 18 years, at the selected ART centre, from the month of June 2018 to December 2018. The sample size calculated was 88 with an absolute precision of 10. Ethical clearance from Institutional Ethics Committee, Andhra Medical College; Written informed consent from all the study participants were taken prior to start of study. Confidentiality of the study participants was maintained. Qualitative variables were presented as proportions. Analytical statistics include chi-square test and regression analysis.

Results: 74% of the patients had a favourable treatment outcome, 15% of the patients died and 11% of the patients were lost to follow up. Occupational status of the study participant, Socio-economic class, tobacco using habit and their CD4 counts had a statistically significant impact on their TB treatment outcome.

Conclusions: CD4 count below 200 cells/mm³, Tobacco use, Diabetes Mellitus- factors responsible for unfavourable treatment outcome of Tuberculosis treatment

Key Messages: Case-specific approaches among LFUs may be carried out to bring improvements in the strategies which are already existing or framing new strategies.

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1. Introduction

Tuberculosis is the most common opportunistic infection amongst HIV-infected individuals. It is a major cause of mortality among patients with HIV and poses a risk throughout the course of HIV disease even after successful initiation of Anti-Retroviral Therapy (ART). TB is one of the leading causes of death in people living with HIV/AIDS.

The advent of HIV has made the diagnosis of TB more difficult.¹

In India 55-60% of AIDS cases reported had TB, and TB is one of the leading causes of death in people living with HIV/AIDS.² Mortality due to HIV-TB co-morbidity was estimated to be 12,000 according to India Tuberculosis report, 2018.

Taking full course of appropriate treatment by the patients plays a key role in management and reduction of

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Tuberculosis infection. In March 2016,³ RNTCP revised its technical and operational guidelines. One of the major additions reflected in terms of strategies is introduction of Daily Regimen in the treatment of Drug sensitive TB under RNTCP. It was started initially among TB-HIV co-infected patients in 2017.

As the treatment outcomes of Daily Regimen are yet novel, the present study was taken up to assess the treatment outcomes of Tuberculosis among TB-HIV co-infected patients and certain factors related to the poorer outcome of the treatment.⁴

2. Objectives of the Study

1. To describe the clinico- epidemiological profile of patients.
2. To assess the treatment outcome among Tuberculosis HIV Co- infected subjects.
3. To identify certain factors associated with poor outcome.

3. Materials and Methods

3.1. Study design

An Observational Longitudinal study.

3.2. Study setting

The study was conducted at an ART centre, attached to King George Hospital in Visakhapatnam District, Andhra Pradesh.

3.3. Study period

From November' 2017 to October' 2019.

3.4. Study population

All the Drug Susceptible TB-HIV co-infected patients, aged above 18 years and newly registered for Fixed Dose Combination therapy of TB treatment under Revised National Tuberculosis Control Programme, at the selected ART centre, from the month of June 2018 to December 2018 constituted the study population.

3.5. Inclusion criteria

1. All TB-HIV co-infected patients newly diagnosed with Drug Susceptible Tuberculosis and put on treatment for Tuberculosis, aged above 18 years.
2. Those who are willing to participate in the study.

3.6. Exclusion criteria

1. Patients aged below the age of 18years.
2. Drug Resistant Tuberculosis cases.
3. Those who are not willing to participate in the study.

3.7. Sample size

Since Treatment outcome assessment was one of the objectives of the study, sample size estimation was done considering the prevalence of treatment success from previous studies which was 67.3%.

The formula used was $n = 4pq/L^2$. Prevalence (p)= 67.3, q (100-p)= 32.7, L= absolute precision = 10

$$N = 4 \times 67.3 \times 32.7 / 10^2 = 88$$

The sample size calculated was 88 with an absolute precision of 10.

3.8. Sampling technique

Out of the 4 ART centres situated in Visakhapatnam district, the study was conducted in the ART centre attached to King George Hospital. All TB-HIV co-infected patients registered for Fixed Dose Combination therapy of Drug susceptible TB treatment at the selected ART centre, from the month of June' 2018 to December' 2018, considering the inclusion and exclusion criteria were included in the study. A total of 93 patients were newly diagnosed with Tuberculosis treatment during the study period i.e., from June 2018 to December 2018, of which 1 patient showed resistance to Rifampicin on CBNAAT and 1 patient aged 10years old. Taking into consideration, the exclusion criteria, the present study included 91 cases. The sample size was calculated as 88 but all 91 cases were included in the study.

3.9. Study variables

1. Socio-demographic characters of all the participants were recorded.
They are -Age, Gender, Education, Occupation, Socio economic status
2. Factors related to Life style of patients that were recorded are as follows:
Weight of the patient, Tobacco usage by the patient, Alcohol intake by the patient, Any co-morbid conditions
3. Disease related factors that were considered were:
CD4 count of the patient, Type of Tuberculosis (New case/ Previously Treated case; Pulmonary Tuberculosis/ Extra pulmonary Tuberculosis), Compliance to TB treatment [Missing more than 2 constitutive weeks of DOTS was taken as non-compliance(5)], Outcomes of Tuberculosis treatment

3.10. Study tools

The study tools used in the study were: A pre-tested interview schedule, weighing machine, Anti- Tuberculosis Treatment (ATT) cards of patients.

3.11. Ethical clearance

Ethical clearance was taken from Institutional Ethics Committee, Andhra Medical College, Visakhapatnam prior to the start of study. Written informed consent was taken from all the study participants who were included in the study in local language. Confidentiality of the study participants was maintained. All the required permissions from the Additional District Medical and Health Officer and Medical Officer of the ART centre were obtained prior to the start of study.

3.12. Data collection and analysis

After obtaining permission from the Head of the Department of Community Medicine; from the Institutional Ethics Committee, Andhra Medical College, Visakhapatnam; from the Nodal Officer, RNTCP, Visakhapatnam district division, Andhra Pradesh and the Chief Medical Officer, ART Centre, King George Hospital, Visakhapatnam, the study was commenced. Informed written consent in the local language, Telugu, was taken from all the patients who were included in the study. For those who were illiterates, the consent was read out & explained to them and consent was obtained by taking their thumb impression in the presence of a witness. All the study participants were given a confirmation that their identity and the obtained data will be kept confidential and will be used purely for academic purpose.

During the full course of tuberculosis treatment, there were 3 interactions with patients. Once at the start of treatment from the month of June 2018, second time at the end of Intensive phase and third time at the end of TB treatment. Basic information regarding socio-demographic details and Life style risk factors were collected by conducting personal interviews of the patients during their first visit at the start of their treatment and the details were noted on pre designed interview schedule. Anti Tuberculosis Treatment (ATT) Records of patients were accessed for information regarding Tuberculosis Type, Treatment Category, CD4 counts at the start of treatment, Co-trimoxazole Prophylactic Therapy. At the end of Intensive phase, patients were assessed for adherence to treatment and at the end of treatment, ATT records were accessed second time for the treatment outcomes of Tuberculosis treatment.

Obtained data was compiled using Microsoft excel sheet and analyzed using SPSS demo version 17. Descriptive statistics for qualitative variables were presented as proportions. Analytical statistics include chi-square test and regression analysis. Treatment outcomes were categorized into 2 groups i.e Favourable outcomes and unfavourable outcomes for analysis purpose. The Outcomes -Treatment Completed and Cured were included under Favourable

4. Results

The analysis was performed with data of 91 patients, who were initiated with Anti Tuberculosis Treatment for Drug susceptible TB, during the study period.

Data accrued from TB-HIV co-infected patients during the study period revealed that participants had the following characteristics: 56% were females and 44% were males; 92.3% cases belonged to 18-50years age group, representing the most socio-economically productive segment of the population.(Table 1)

A past history of TB has already been documented in 19% of the study population, 41% of the cases manifested with extra-pulmonary TB, 87% of the cases diagnosed with TB-HIV co-infection had their CD4 counts ≤ 500 cells/mm³.

Non-compliance to TB treatment was observed among 13 patients of which 10 were categorised as LFU, as they were non-compliant to TB treatment for >1month and could not be traced later on, in spite of being on 99DOTS tracking system. The other 3 patients have completed their ATT with noncompliance episodes in between treatment.

Non-compliance was found to be higher among Males, Unemployed people, patients with Primary level of education and belonging to Middle class according to B.G.Prasad's scale for Socio-economic classification, Non-diabetics, Non- Tobacco users, Non- Alcoholics, Pulmonary TB patients and New cases of Tuberculosis.

The reasons uncovered for non-compliance to treatment, through the telephonic conversation with patients as stated by them were:

1. Long distance was the reason stated by 2 of the patients.
2. 2 patients did not have attendant for accompanying them to ART centre.
3. 1 person was out of town for a month and had continued taking treatment after returning back to the city.

After completion of Tuberculosis treatment, nearly 74% of the patients had a favourable treatment outcome (Treatment completed-65% and Cured-9%), 15% of the patients died during the treatment and the rest i.e 11% of the patients were Lost to follow up.(Table 2)

Among various study variables, occupational status of the study participant, Socio- economic class to which the study participant belonged, tobacco using habit of the individual and their CD4 count had a statistically significant impact on their TB treatment outcome.(Table 3)

4.1. Factors influencing tuberculosis treatment outcome

A logistic regression was performed with factors which might influence the tuberculosis treatment outcome. Independent variables used for calculating logistic regression were Gender, Diabetes Mellitus status, CD4

values, Alcohol and Tobacco use by the study participant.

The model was found to be fit for conducting logistic regression with an Omnibus $\sum^2$ value of 2.780, which is significant.

The overall predicted percentage is 75.8% with Nagelkerke's R^2 value of 0.421.

From table 4 we can conclude that,

- 1. A person with CD4 count below 200 cells/mm³ has 13.851 times higher risk of developing an unfavourable treatment outcome when compared to those with CD4 count above 200cells/mm³.
- 2. A person who is a tobacco user is at 8.978 times high risk of developing an unfavourable outcome when compared to non-tobacco users.
- 3. The chances of a diabetic developing an unfavourable outcome is 1.326 times higher than that of a non diabetic person.

5. Discussion

In the present study, majority of the cases belonged to <50 years age group, representing the socio-economically productive age group. Similar observations were also reported in the studies by R.Ghiya et al,⁵ Magnbosco GB et al,⁶ Mehretu et al.⁷

Majority of the patients in the present study were compliant to the treatment (85.7%). Similar to the present study higher proportion of compliance to TB treatment was also observed in study conducted by Rai. N et al.⁸

Higher proportion of favourable treatment outcome were observed among non-tobacco users (80%) in the present study. Similar findings were also observed in Magnabosco GB et al study.⁶

77.2% of non-alcoholics had favourable treatment outcomes in the present study. Similar findings were also observed in a study conducted by Magnabosco GB et al⁶ study.

In studies done by Minaleshwa et al,⁹ Mehretu et al⁷ and Sinshaw et al.,¹⁰ successful treatment outcomes were higher among higher weight band categories similar to the findings as observed in the present study.

In the present study, Extra - pulmonary TB patients had higher proportion of unfavourable outcome with 29.7%. Previously treated cases had higher proportion of favourable outcome (76.5%) which may be due to prior health education regarding importance of adherence to treatment from the health personnel which is comparatively newer among New cases of TB. Apart from this, new cases required higher motivation for treatment adherence in order to overcome their behavioural attitude towards the disease.¹¹

In contrast to the findings of the present study, Unfavourable outcomes were high among Pulmonary

Table 1: Clinico- epidemiological profile of study participants

S.No.	Study Variable		Number (%)
1.	Gender	Male	40(44)
		Female	51(56)
		18-30	20(22)
2.	Age (in years)	31-40	40(44)
		41-50	24(26.3)
		51-60	7(7.7)
		Illiterate	24(26.3)
3.	Education	Primary	16(17.6)
		Secondary	23(25.3)
		Intermediate	10(11)
		Degree & Above	18(19.8)
4.	Occupation	Employed	48(52.7)
		Unemployed	43(47.3)
5.	Socio-Economic Class	Upper class	33(36.2)
		Middle class	38(41.8)
		Lower class	20(22)
6.	Diabetes Mellitus	Yes	13(14.3)
		No	78(85.7)
7.	Tobacco usage	Yes	26(28.6)
		No	65(71.4)
8.	Alcohol intake	Yes	34(37.4)
		No	57(62.6)
		25-39	30(33)
9.	Weight band(in kgs)	40-54	52(57.1)
		55-69	7(7.7)
		≥70	2(2.2)
10.	Type of Tuberculosis based on site of TB	Pulmonary TB	54(59)
		Extra-Pulmonary TB	37(41)
11.	Type of Tuberculosis based on prior TB treatment	New case	74(81)
		Previously Treated case	17(19)
12.	CD4 count	≤500cells/mm ³	79(87)
		>500cells/mm ³	12(13)
13.	Treatment Compliance	Compliant	78(85.7)
		Non- compliant	13(14.3)

Table 2: Distribution of study population basedon treatment outcome

Variable		Frequency (%)	
Treatment Outcome	Treatment Completed	64.8	Favourable Outcome
	Cured	8.8	
	Loss to Follow up	11	Unfavourable Outcome
	Died	15.4	

Table 3: Distribution of treatment outcome among various study variables

S.No.	Study Variable		Favourable treatment outcome	Unfavourable treatment outcome	P value
1.	Gender	Male	31	9	0.45
		Female	36	15	
2.	Age (in years)	18-30	15	5	0.27
		31-40	30	10	
		41-50	19	5	
3.	Education	51-60	3	4	0.07
		Illiterate	14	10	
		Primary	12	4	
		Secondary	24	9	
4.	Occupation	Degree & Above	17	1	0.02
		Employed	40	8	
		Unemployed	27	16	
5.	Socio-Economic Class	Upper class	30	3	0.01
		Middle class	28	10	
		Lower class	9	11	
6.	Diabetes Mellitus	Yes	8	5	0.28
		No	59	19	
7.	Tobacco usage	Yes	15	11	0.02
		No	52	13	
8.	Alcohol intake	Yes	23	11	0.3
		No	44	13	
9.	Weight band (in kgs)	25-39	18	12	0.18
		40-54	41	11	
		55-69	6	1	
		≥70	2	0	
10.	Type of Tuberculosis based on site of	Pulmonary TB	41	13	0.54
		Extra-Pulmonary TB	26	11	
11.	Type of Tuberculosis based on prior TB treatment	New case	54	20	0.76
		Previously Treated case	13	4	
12.	CD4 count	≤500cells/mm ³	55	24	0.02
		>500cells/mm ³	12	0	

Table 4: Factors influencing tuberculosis treatment outcome

Factor	Odds Ratio	95% C.I for Odds Ratio	
		Lower	Upper
CD4 count (cut off 200cells/mm ³)	13.851	2.236	85.795
Alcohol usage	0.193	0.023	1.649
Tobacco usage	8.978	1.088	74.078
Diabetes mellitus	1.326	0.282	6.232
Gender	0.962	0.223	4.151

Tuberculosis cases in Jackson et al and among Previously treated cases in Minaleshwa et al study.⁹

1. CD4 count below 200cells/mm³ with 13.851 times higher risk.
2. Tobacco use with 8.978 times higher risk.

6. Conclusion

In the present study, the factors responsible for unfavourable treatment outcome of Tuberculosis treatment among TB-HIV co-infected patients that were observed were:

7. Recommendations

1. Factors associated with Unfavourable treatment outcome were Tobacco use, Diabetes Mellitus, Unemployment, and Lower Socio-economic class,

which are amenable for modification. Tobacco cessation centres/ counsellors should be associated with the programme to deal with Tobacco users.

2. Further in-depth studies should be carried out for unmasking the reasons for differences in the cure rates among the gender of the population.
3. 99 DOTS may be strengthened by providing an alternate method for delivery of drugs by which compliance to treatment may be improved among the population who cannot access the TB treatment due to any reasons.
4. Further studies like case-specific approaches among LFUs may be carried out to bring improvements in the strategies which are already existing or framing new strategies.

8. Conflict of Interest

None.

9. Source of Funding

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