Original Research Article

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Study of treatment outcome of tuberculosis among HIV co-infected patients: a cross sectional study in Aurangabad city, Maharashtra

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ABSTRACT

Background: Tuberculosis is the most common presenting illness among people living with HIV, including those who are taking anti-retroviral treatment. There were an estimated 1.2 million HIV positive new TB cases globally in 2014. Around 74% of these infected people live in sub-Saharan Africa. Aim and objectives were to study the treatment outcome of tuberculosis among HIV co-infected patients; to assess the outcome of TB treatment in TB patients with respect to their HIV status and to study the underlying factors influencing the outcome rates.

Methods: A descriptive cross-sectional study was designed and conducted in Municipal Corporation area, Aurangabad. For this study, HIV co-infected patients registered at city Tuberculosis Centre, Aurangabad were noted and thus information only on TB-HIV status of patients was collected.

Results: In this study majority of the study participants were in the age group between 35 and 49 years (45.98%); which is in the reproductive age group. HIV-TB co-infected in this region was mostly males (60.92%).

Conclusions: Important conclusion of the study is that very few patients got cured off TB among TB-HIV co-infected patients. One of the reasons could be immunosuppression of HIV patients make them vulnerable for getting active TB and its rapid progression. All the rates i.e. death, default & transfer rate are all above the standard rate i.e. 5% as per RNTCP guidelines.

Keywords: Treatment outcome, Tuberculosis, HIV, ART, CPT

INTRODUCTION

Tuberculosis is the most common chronic illnesses among people infected with HIV, including those on antiretroviral treatment. There were about 1.2 million HIV positive new TB cases reported globally in the year 2014. Near about 74% of these infected patients live in sub-Saharan Africa. Globally HIV associated TB deaths in 2014 were higher among males than in females.

Globally patients living with HIV are more prone to develop active TB disease than those living without HIV.

If diagnosis is delayed, HIV infected patients are at increased risk of getting. Multi drug-resistant (MDR-TB) and extensively drug-resistant Tuberculosis (XDR-TB) ¹

Three I's for HIV-TB co-infection (Intensified case finding for TB, Isoniazid preventive therapy (IPT) and Infection control) will be very helpful in reduction of the burden of TB among the people living with HIV and therefore it must be urgently dealt with by policy makers at all health facilities giving HIV health care services. HIV infected patients who were recorded, have been screened for active Tuberculosis (component of

"intensified case finding") increased from 5.5 million cases in 2013 to around 7 million cases in 2014.

Early diagnosis and prompt treatment among people living with HIV is an essential factor for decreasing TB associated morbidity and mortality. World Health Organization (WHO) suggests. The use of X pert MTB/RIF as the most important initial diagnostic test for diagnosing people infected with HIV and TB. ¹

Global HIV-TB co-infection

Total 400,000 patients who had suffered from both HIV& TB have died in the year 2015, in comparison to those 1.4 million cases who died of tuberculosis alone.² In total about 1.2 million patients died of HIV infection in the year 2014. Globally about 11% new TB cases were registered in the year 2015, out of all patients living with HIV and they started with both anti-retroviral and anti TB treatment.³

For adults suffering from TB and HIV need to receive both anti-retroviral and anti-TB drug therapy, WHO guidelines suggests to use HIV anti-retroviral therapy between 2 to 8 weeks after starting TB treatment for those individuals with a CD4 cell count less than 200 mm. ^{4,5} Stop TB Partnership global plan to stop TB has a target, that all HIV-TB co-infected patients should receive anti-retroviral treatment regularly by 2015. ⁶

India scenario

HIV positive patients co-infected with Tuberculosis are having 20 to 40 times more chances to get an active TB disease than those not infected with HIV residing in the same geographical area. Tuberculosis is a leading cause of death in HIV positive patients leading to more than a quarter of 2 million AIDS deaths in year 2008; globally it is the commonest HIV associated opportunistic infection; as it facilitates infectivity, HIV disease progression and decreases efficacy of anti-retroviral therapy.

In India, there were 2.5 million patients living with HIV and AIDS in 2007, while the incidence of new TB cases was about 1.8 million cases per year. ¹¹The level of immunosuppression in patients determines clinical profile of the disease. ^{12,13} Pulmonary infection is common and involved in about 75% of all co-infected patients. ¹⁴ HIV-TB co-infection finally results in more rapid progression to severe forms of MDR and XDR Tuberculosis. ¹⁵

Aim

To study treatment outcome of Tuberculosis among HIV co-infected patients.

Objectives

1. To assess the outcome of TB treatment in TB patients co-infected with HIV.

2. To study socio-demographic profile with reference to age, gender and registration status of TB patients coinfected with HIV.

METHODS

Study design: Descriptive Cross-sectional Study

Study settings: Municipal Corporation, city area, Aurangabad.

Study population: Total 87 HIV-TB co-infected patients were selected for the study out of all patients who have diagnosed with Tuberculosis.

Sampling technique: A retrospective study of all available secondary data of diagnosed TB-HIV coinfected cases registered at the city Tuberculosis Centre, Aurangabad city in one calendar year and who had successfully completed TB treatment. Universal purposive sampling was used.

Method of data collection: The data collected for this study was patients registered at city Tuberculosis Centre, Aurangabad city. We had contacted city TB officer through proper channel with due permission from institute authority for getting information of TB-HIV coinfected patients in Aurangabad city only, thus only HIV co-infected patients registered at city Tuberculosis Centre, Aurangabad were noted and information of patients was collected.

Inclusion and exclusion criteria: We have included participants irrespective of age and gender and excluded those who have been suffered from any other chronic comorbid conditions or diseases, other than HIV; as it was not intended to show the relationship between HIV patients and other co-morbid conditions or diseases.

Plan of the study: This was a retrospective cross-sectional study using routine program data from city TB centre Aurangabad, Maharashtra, India. Aurangabad city has a population of 1248656 as per census 2011; having in total 1194 TB patients registered during year 2015. Local RNTCP governing body follow a strategy of provider-initiated HIV testing and counseling for all patients registered for TB treatment as recommended by WHO and UNAIDS; while TB treatment is initiated under the TB program at a treatment center close to the patients residence, the TB treatment and patient response is also monitored by the ART center physician in case of co-infected patients.

Records of all HIV co-infected TB patients registered at city TB center from 1st Jan 2015 to 31st December 2015 were collected & analyzed. In the Aurangabad city, the TB patients registered under the Revised National TB control program are treated with standardized fully intermittent thrice weekly short-course regimens administered under direct observation (DOTS) and are

registered at one of the 2 sub-district TB program management units (TU) according to RNTCP guidelines.

Operational definitions

- TB infection: Infection with Mycobacterium Tuberculosis bacilli.
- Active TB disease: Presence of signs and symptoms of TB disease in an individual who is infected with Mycobacterium Tuberculosis bacilli.
- Case of tuberculosis: A definite case of TB (a pulmonary TB case with one or more initial sputum smear examinations positive for acid-fast bacilli) or one in which a health worker (clinician or other medical practitioner) has diagnosed TB and has decided to treat the patient with a full course.
- HIV infection: Infection with the Human Immunedeficiency Virus (HIV) that is confirmed by approved serologic tests.
- *TB/HIV co-infection:* The presence of both TB and HIV infection in an individual patient
- *TB treatment outcome:* The final known status of a TB patient who was started on anti-TB treatment.
- *Cured:* An initially smear-positive patient who is sputum smear-negative at, or 1 'month' prior to, the completion of TB treatment and on at least one previous occasion (usually at the end of the 2nd or 5th month).
- Treatment completed: Patient who completed anti-TB treatment without evidence of failure but for whom sputum smear or culture results are not available in the last month of treatment and on at least one previous occasion.
- Treatment failure: Patient whose sputum smear or culture is positive at 5 months or later during

- treatment. Also included in this definition are patients found to harbour a multidrug-resistant (MDR) strain at any point of time during the treatment, whether they are smear-negative or positive.
- *Defaulter:* A patient who has been on treatment for at least 4 weeks and whose treatment was interrupted for 8 or more consecutive weeks.
- Died: A patient who dies for any reason during the course of treatment.
- *Transfer out:* A patient who started treatment and has been transferred to another reporting unit and for whom the treatment outcome is not known at the time of evaluation of treatment results.
- Treatment success: The sum of patients who are declared 'cured' and those who have 'completed' treatment.¹⁶

RESULTS

Out of Total 1194 TB patients registered during 1st January 2015 to 31st December 2015 the 87 co-infected patients for whom data on TB treatment outcomes was available, 63.21% patients completed the treatment successfully; of the remaining 25 patients, 16.02% had cured. A total of 9.19% patients had defaulted, there were 7 deaths (i.e. 8.05%), and transferred out were 6.89%. Proportion of HIV - TB cases among total 1194 TB cases registered during 1st January 2015 to 31st December 2015 was 87 (7.28%) registered by city TB centre.

It was found that all the patients (100 %) were put on treatment with Co-trimoxazole preventive therapy (CPT) and Anti- retroviral therapy (ART).

Table 1: Socio-demographic profile with reference to age, gender, health facility and outcome of treatment among respondents (n=87).

Parameter		Number	Percentage
Age (in years)	0-14	05	5.74
	15-24	07	8.05
	25-34	28	32.19
	35-49	40	45.98
	50-64	04	4.60
	64-90	03	3.45
Gender	Male	53	60.92
	Female	34	39.08
Registration at Health facility	Government sector	29	33.33
	Private sector	58	66.66
Outcome of treatment	Cured	14	16.09
	Treatment completed	55	63.21
	Died	07	8.05
	Transferred out	03	6.89
	Defaulted	08	9.19
Co-trimoxazole preventive therapy (CPT)		87	100
Anti- retroviral therapy (ART)		87	100
Total		87	100

Treatment outcome	Gender		Chi square test
	Male	Female	
Cured	11	3	Chi-square value=6.96
Treatment completed	35	20	p=0.138 df=4
Died	2	5	d1=4
Transferred out	2	1	
Default	3	5	
Total	53	34	

Table 2: Gender wise treatment outcome among respondents (n=87).

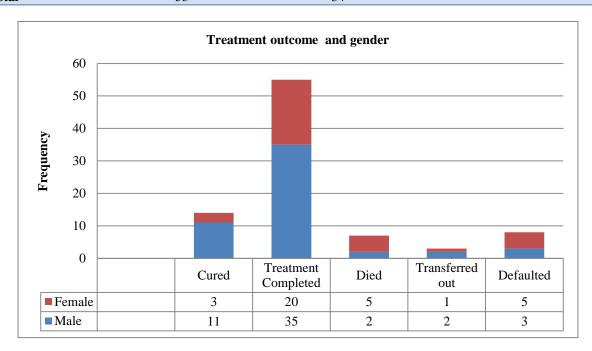


Figure 1: Treatment outcome of study subjects as per gender (n=87).

Table 2 shows that most of the male patients had completed TB treatment as compared to female patients. Gender status (whether male or female) was not found to be significantly associated with the treatment outcome among the patients (p=0.1380)

In this study majority of the study participants were in the age group between 35 and 49 years (45.98 %); which is in reproductive age group. TB-HIV co-infected in this region was mostly males (60.92%) and 39.08% were females. Prevalence of TB-HIV co-infection is found to be 7.28 %.

Most of the patients (66.66%) were registered and treated at private hospitals and total of 33.33% patients were registered as well as treated government hospitals.

The most important findings are that only 16.09% got cured which is very less compared with standard cure given by RNTCP.

Another finding was that all the rates i.e. death (8.05%), default (9.19%) and transfer rate (6.89%) are all above the standard rate i.e. 5% as per RNTCP guidelines.

DISCUSSION

Globally and in India, TB is one of the most common opportunistic infections affecting people with HIV. This assumes importance in a country like India which has 2.7 million HIV infections and 23% of the world's incident TB cases. HIV infection is often cited as an important reason for failure to control TB, and for causing resurgence in TB worldwide. While this is true, our results suggest that implementation of program guidelines in a coordinated manner can result in good treatment outcomes among those co-infected with HIV.

In present study maximum respondents were in the age group between 35 and 49 years (45.98%); which is in reproductive age group. HIV-TB co-infected in this region was mostly males (60.92%). Most of the patients were registered and treated at private hospitals while remaining patients were registered in Government institutes. The most important study finding was that only 16.09% patients got cured which is very less compared with standard cure rate set by RNTCP i.e. 85%. One of the reasons could be immunosuppression of HIV patients make them vulnerable for getting active TB and its consequent rapid progression. All the rates i.e. death,

default & transfer rate are all above the standard rate i.e.5% as per RNTCP Guidelines. Most of the male patients had completed TB treatment as compared to female patients. Thus gender status (whether male or female) was not found to be significantly associated with the treatment outcome among the patients (p=0.1380). It was found that all the patients (100%) were put on treatment with Co-trimoxazole preventive therapy (CPT) and anti-retroviral therapy (ART).

Dagnra et al in his study titled as, prevalence of HIV-TB co-infection and impact of HIV infection on pulmonary tuberculosis outcome in Togo. Of the total TB patients enrolled, HIV prevalence was lower among men as compared to that of women without any statistical significance. The overall global rate of tuberculosis treatment success was found to be higher 82.2%.

Deivanayagam et al studied clinic-radiological spectrum of tuberculosis among HIV sero-positives a Tambaram study. Study shows that tuberculosis was found to be the predominant co-infection among the symptomatic patients infected with HIV attending the largest care center for the first time in India. Early detection of tuberculosis co-infection is absolutely necessary; same is true for our study, as cure rate is low in TB/HIV co-infected patients i.e. only 16.09 %. ¹²

In a similar study conducted by Ahmad et al, one hundred thirty consecutive patients of tuberculosis co-infected with HIV were included in this study. One hundred ten (84.6%) patients were males and the rest 20 (15.4%) were females. Their age ranged from 18 to 70 yrs (mean 29). Eighty (61.54%) patients had pulmonary tuberculosis alone and 26 (20%) had extra-pulmonary tuberculosis alone while 24 (18.46%) patients had both pulmonary and extra-pulmonary tuberculosis. ¹³

In the study of Ali et al out of the total TB patients enrolled in the study, proportion of HIV non-infected patients were higher to that of HIV co-infected. In our study the prevalence of TB-HIV co-infection is found to be 7.28%. They found that, treatment success rate was somewhat lower i.e. 88.2% in HIV co-infected TB patients when compared to those 93.6% study respondents who were not infected with HIV; while treatment success rate was found to be less in proportion in our study i.e. 63.21% in HIV co-infected patients. Also HIV co-infected TB patients had a significantly higher rate of unfavorable outcomes similar to the present study. The cure rate was significantly lower 18.4% and the death rate was higher in HIV co-infected TB patients i.e. 4.7% which was in conformity with our study.

CONCLUSION

Important conclusion of the study is that very few patients got cured off TB among TB-HIV co-infected patients. One of the reasons could be immunosuppression of HIV patients make them vulnerable for getting active TB and

its rapid progression. All the rates i.e. death, default and transfer rate are all above the standard rate i.e. 5% as per RNTCP guidelines. All the study findings shows that there is strong need to evaluate and strengthen the RNTCP services in order to achieve the expected rates given by RNTCP for getting ultimate success, as day by day the HIV-TB is burning public health problem. TB-HIV co-infection epidemic is a public health concern which can be decreased with effective linkage between RNTCP and NACP. Prompt diagnosis and treatment of active TB patients will help in bringing down the morbidity and mortality associated with TB-HIV coinfection. Further studies will be needed to analyze the reasons why after receiving complete CPT and ART for treatment have no effect on TB treatment outcomes of HIV co-infected TB patients. Delay in diagnosis and complete treatment of HIV and/or TB might have worsened outcome of these patients.

Limitations

- Limitation is that the data collected is retrospective secondary data. For some study respondents, there were issues like missing and/or getting inaccurate information.
- Further prospective studies are required to explore additional delivery of services and factors affecting patient compliance that may affect the outcome of HIV co-infected TB patients.

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Institutional Ethics Committee

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