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## RESEARCH ARTICLE

### A Retrospective Study on Treatment Outcome of Tuberculosis and HIV Co-Infection

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#### ABSTRACT

**Objective:** To study the treatment outcome of tuberculosis and hiv co-infection including the various ADRs & Drug Interactions that occur during the co treatment of the disease with Anti tubercular drug and Anti-retroviral therapy. **Method:** An observational and active surveillance study was conducted in the Govt. general and chest hospital for over a period of six months. The information obtained was recorded in the data collection form and analyzed. **Results:** Descriptive statistical analysis have been carried out to generate the results. Results on categorical measurement are presented in (%). The results showed that the prevalence of ADR's was about 84% and the drug interactions was found to be 73%. **Conclusion:** This highlighted the importance of developing strategies to amyliorated and drug drug interactions both to improve the quality of patient care and to control tuberculosis and HIV co-infection safely.

**Key words:** prevalence, HIV, adverse drug reaction, drug drug interaction

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#### 1. Introduction

Tuberculosis and HIV co infections place and immense burden on health care systems and pose particular diagnostic and therapeutic challenges.[1] TB and HIV co infection Is when people have both TB as well as active or

latent TB disease. One disease progresses other disease. Infection of HIV is the most powerful known risk factor predisposing for Mycobacterium tuberculosis infection.[1] This co infection accounts for many deaths in the world. Co

infection with TB does not occur unless a person comes in contact with a patient that has TB or live in an area with high prevalence of TB such as India or South Africa. The incidence of TB is currently increasing in HIV infected patients living in Africa and Asia.[2] The proportion of known co-infected patients and on the therapy is 78% globally and over 90% in India.

In the last 15 years the number of more TB cases has more than doubled in countries with HIV infections so high.[3]

In India, the overall prevalence of HIV infection is less than 1 per cent and India continues to be in the category of low prevalence countries. TB results by infection from a pathogen called Mycobacterium tuberculosis. The penetration bacteria into the respiratory tract infects the macrophages while CD4 or T-lymphocytes produce interferon gamma (IFN), interleukin-2, tumor necrosis factor alpha and macrophage colony stimulating factor that activate macrophages and cytotoxic cells to inhibit their intercellular growth. During HIV infection, IFN-production is decreased dramatically in parallel with reduction of CD4 T-lymphocytes which results in an increased risk of developing TB or relapse of TB.[4]

This is manifested based on stages: The symptoms of TB include cough, progressive fatigue, malaise, weight loss, night sweats and low grade fever.

The symptoms of HIV are further divided according to the 4 stages of the disease that are as follows:

**Stage 1** – also called as the acute primary infection constitutes of fever, body rash, sore throat, swollen glands, headache, upset stomach.

**Stage 2** – the asymptomatic stage does not show any symptoms for a period of around 10 to 15 years.

**Stage 3** – it includes weight loss, chronic diarrhea, night sweats, fever, persistent cough, mouth and skin problems, infections, serious illness

**Stage 4** – the final stage is the most severe form of the illness[5]

The treatment of TB is also more difficult to manage in HIV infected patients, particularly with regard to pharmacological interactions with rifampicin or rifabutin, respectively. The treatment of co-infected patients requires antituberculosis and antiretroviral drugs to be administered concomitantly; challenges include pill burden and patient compliance, drug interactions, overlapping toxic effects, and immune reconstitution inflammatory syndrome.[6 ,7, 8].

## 2. Materials and Methods

**Study Type:** A retrospective observational study

**Statistical Method:** SPSS

**Study Duration:** The data of the patients attending ART center, during 6 months study period (i.e. from October 2018- March 2019).

**Sample Size:** The present study was conducted on 164 patients who visited ART center of Government general and chest hospital

**Study Site:** The study was conducted in the outpatient department of ART center of Government General and Chest Hospital, Hyderabad, India.

**Study Criteria**

### Inclusion Criteria:

- Patients above the age of 18.
- Patients of either sex.
- Patients having a family history of TB.
- Patients who are willing to give verbal informed consent for the study.
- Patients diagnosed with pulmonary and extra-pulmonary TB.
- Patients who are co-infected with HIV.
- Patients on DOTS therapy

### Exclusion Criteria:

- Patients under the age of 18.
- Pregnant and lactating women.
- Patients who are not willing to give information.

### Sources of Data:

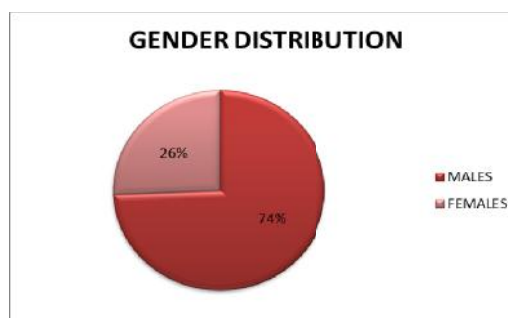
- Treatment chart or case sheet.
- Patient data collection form.

## 3. Results and discussion

### Gender Distribution:

**Table 1:** Gender Distribution

S.No	Gender	Number of Patients	Percentage
1.	Males	122	74%
2.	Females	42	48%
3.	Total	164	

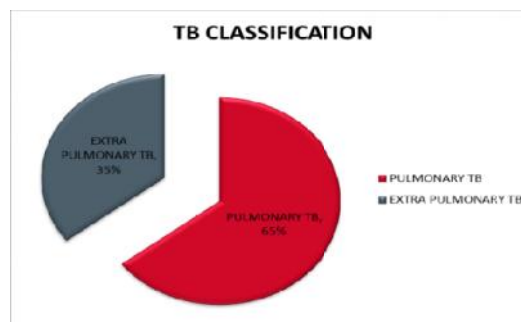


**Fig 1:** Gender distribution

Out of the total 164 patients, that were diagnosed with tuberculosis and HIV coinfection, the number of males found to be were {n=122} and number of females were {n=42}. The co-infection was found predominant in the males than females.

**Table 2:** Classification of TB

Type of TB	Patients	Percentage
Pulmonary TB	106	65%
Extra Pulmonary TB	58	35%

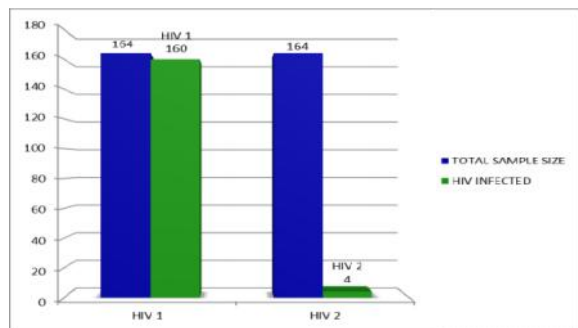


**Fig 2:** Patient data based on classification of TB

Tuberculosis is mainly classified into two categories, pulmonary tuberculosis and extra pulmonary tuberculosis that involves the spreading of the bacteria and infection apart from the lungs. Of the total patients, {n=106} were diagnosed with pulmonary TB and {n=58} were diagnosed with extrapulmonary tuberculosis. The prevalence of pulmonary tuberculosis with HIV coinfection is however found higher than the latter.

**Table 3:** Patient data based on HIV type

Type of HIV	Number of Patients	Percentage
HIV 1	160	97%
HIV 2	4	3%

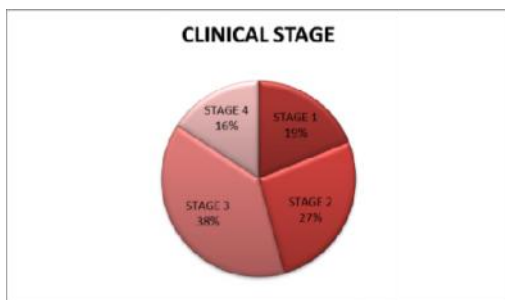


**Fig 3:** Patient data based on HIV type

The patients with HIV 1 were found predominant in the analysis.

**Table 4:** Patient data based on clinical stages of HIV

Clinical Stage of HIV	Number of Patients	Percentage
Stage 1	31	19%
Stage 2	44	27%
Stage 3	63	38%
Stage 4	26	16%

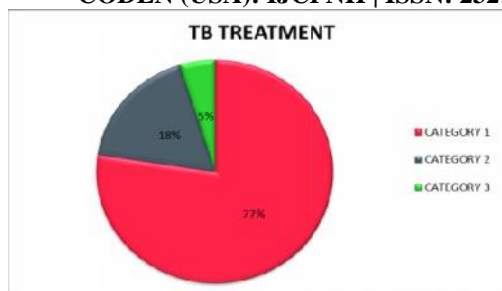


**Fig 4:** Patient data based on clinical stages of HIV

The HIV patients are clinically diagnosed based on the stages at which they are present based on the symptoms presented. Most of the patients were found to be at stage 3 {n=63} and the least were at the clinical stage 4 {n=26}.

**Table 5:** Patient data based on TB treatment given

Treatment Given	Number of Patients Receiving The Treatment
Category I	127
Category II	29
Category III	08

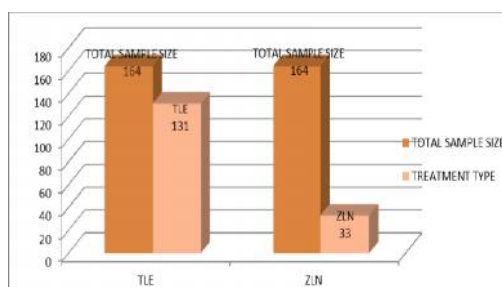


**Fig 5:** Patient data based on TB treatment given

The patients received anti-tubercular treatment which is further of three categories. Most of the patients {n=127} patients were given with category I treatment.

**Table 6:** ART therapy given to the patients

Art Therapy Given	Number of Patients Receiving Art Therapy
TLE	131
ZLN	33

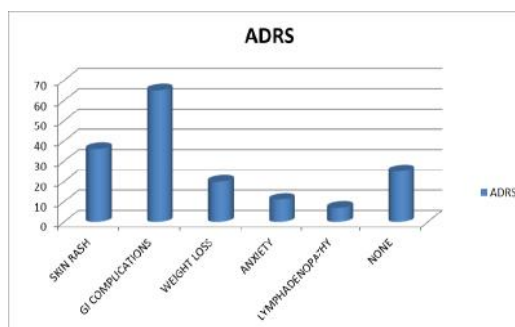


**Fig 6:** ART therapy given to the patients

Out of the 164 patients, {n=131} patients received TLE that is a combination of tenofovir, lamivudine and efaviranz and {n=33} received ZLN that is a combination of zidovidine, lamivudine and nevirapine.

**Table 7:** Adverse drug reactions observed in the patients

S.No	Type of Adverse Effect Seen	Number of Patients with the ADR
1.	Skin Rash	36
2.	GI Complications	65
3.	Anxiety	11
4.	Lymphadenopathy	7
5.	Weight Loss	20
6.	None	25
Total Of Showing ADRS		139

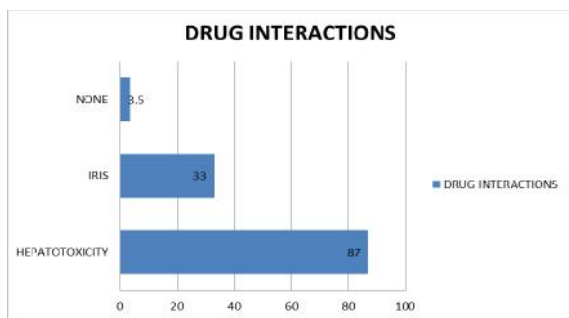


**Fig 7:** Adverse drug reactions observed in the patients

Out of the 164 patients a number of patients have shown adverse effects, skin rash {n=36}, weight loss {n=20}, GI complications {n=65}, anxiety {n=11}, lymphadenopathy {n=7} and none {n=25}.

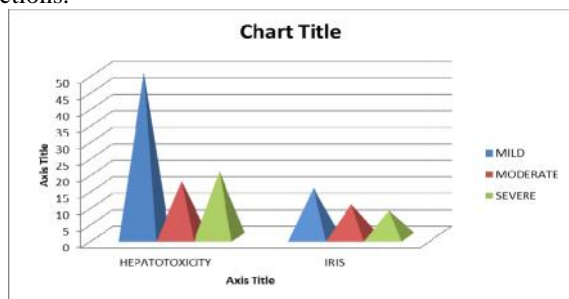
**Table 8:** Drug interactions occurred

Drug Interaction Type	Number of Patients In Which the Interaction Occurred
Hepatotoxicity	87
Iris	33
None	45



**Fig 8:** Drug interactions occurred

Out of the 164 patients, 120 patients showed drug interactions, with {n=87} showing hepatotoxicity and {n=33} patients showed IRIS. The drug interactions are further divided into mild, moderate and severe type of reactions.



**Fig 9:** Severity of the reactions that occurred

**Discussion**

TB/HIV co-infection represents a novel pathogenic scenario at the global level. It constitutes a serious diagnostic and therapeutic challenge and, particularly in poor countries, weighs heavily on already strained health care budgets.[1] In a study span of 6 months carried out in Government General and Chest Hospital, Hyderabad, India, the demographic parameters including gender were analyzed. The males were found more prevalent to the females by 74%. The patients were also classified based on the classification of TB as their diagnosis. Pulmonary TB was found more prevalent (65%). The patients were also classified and analyzed based on the type of HIV. HIV1 was found in most number of patients 97%. The clinical stage III was found 38% and as maximum in the patients. The TB treatment was given with Category I in maximum patients 77% followed by Category II in 17% of the patients. The antiretroviral therapy was given with a combination of Tenofovir + Lamuvidine + Efavirenz (TLE) International Journal of Medicine and Pharmaceutical Research

in maximum number of patients 80%, followed by a combination of Zidovudine + Lamuvidine + Nevirapine in 20% of the patients. The Adverse Drug Reactions were also observed. GI complications were found in maximum number of patients 40% followed by skin rashes 22%, weight loss in 12% patients. Anxiety and Lymphadenopathy were also seen in a few patients. 15% patients were seen with no specific adverse drug reactions. Drug Interactions were also observed in patients due to the co treatment of Anti-tubercular and Antiretroviral therapy. 73% of the patients were seen with drug drug interactions out of the total patients. Out of the total patients, hepatotoxicity was observed in 53% patients, Immune reconstitution inflammatory syndrome in 20% patients. And the rest did not show any drug interactions. Some patients showed mild reactions 50% of hepatotoxicity and 9% of IRIS.

**4. Conclusions**

The worldwide incidence of TB is increasing currently, particularly in areas of the southern hemisphere where HIV epidemics are devastating because anti-retroviral therapies are not available. HIV-infected patients are at extremely high risk for progression from latent TB to active disease, and unusual clinical manifestations of TB should not be ignored in this high-risk group. Patients receiving HAART may have significant drug–drug interactions when rifampicin is used with PIs or NNRTIs, and also risk developing severe paradoxical reactions attributable to immune restoration. This conditions of the patients occurring due to the co treatment of the co infection should be taken into account.

**5. Acknowledgement**

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