# Response of Tuberculosis to DOTS Therapy in People Living with HIV/AIDS: A Prospective Clinical Study

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# ABSTRACT

**Background:** In the patients with HIV and concomitant tuberculosis (TB), the response to directly observed therapy-short course (DOTS) is variable because of immunosupression, opportunistic infections and intolerance due to drugs including anti-retroviral treatment (ART).

**Aim:** To study the response of TB to DOTS in immunosupressed patients with HIV.

**Material and Methods:** Patients who attended our department during 2009-2010 with respiratory symptoms were screened. Study group comprised patients diagnosed with HIV with TB. Study group was further divided in A-CD4 count <150/ cmm, receiving DOTS with ART and B- CD4 count >150/cmm,

INTRODUCTION

Tuberculosis (TB) is a serious public health problem in India, now further flared up by concomitant HIV infection. According to WHO, 5% of TB patients in India are co-infected with HIV [1]. In the presence of HIV, the response of TB to anti-tubercular therapy (ATT) is variable because of immunosupression, opportunistic infections and drug interactions. We are reporting here the clinical and investigational response to the ATT among the patients with concomitant HIV and TB infections.

#### **METHODS AND MATERIALS**

The prospective cohort study was conducted at Revised national tuberculosis control program (RNTCP) Centre in collaboration with the department of Chest and Tuberculosis, Konaseema Institute of Medical Sciences, Amalapuram between year 2009 and 2010.

All patients with cough and expectoration were screened with chest x-ray, sputum examination and appropriate pathological investigations (e.g lymph node biopsy, pleural fluid analysis) to establish the diagnosis. All TB patients were screened for HIV. The patients with concomitant HIV and TB infections (study group) were further divided into those on anti-retroviral therapy (ART) along with directly observed treatment- short course (DOTS) (group A) or only DOTS (group B) on the basis of CD4 cell count less than (A) or more than (B) 150/cmm. Patients with tuberculosis without associated HIV infection were taken as controls. All these patients were treated with DOTS category 1 of RNTCP regimen, 2 (EHRZ) + 4(HR) thrice weekly for 6 months. While on therapy patients were evaluated at 2 monthly intervals for 6 months for clinical improvement, sputum microscopy, ESR and chest X-ray.

receiving DOTS alone. Control group comprised patients with TB alone, on DOTS.

**Results:** Three hundred and forty three patients were diagnosed with TB of which 37, diagnosed with HIV with TB, were included in study (7 with CD4 count <150/cmm, receiving DOTS with ART and 30 with CD4 count >150/cmm, receiving DOTS alone). Control group comprised of 306 patients with TB alone, on DOTS. In the study group, of 7 patients in subgroup A, 2 patients died and 5 patients defaulted. All 30 patients in subgroup B were improved. Improvement was observed in all patients in control group.

**Conclusions:** Concomitant use of DOTS and ART increase in the incidence of therapy default to DOTS otherwise six months of therapy is enough to cure TB in HIV cases.

Key Words: Koch's, AIDS, Compliance

# RESULTS

During the study period, 343 patients were diagnosed with TB of which 37 werediagnosed with HIV with TB, were included in study (7 with CD4 count <150/cmm, receiving DOTS with ART and 30 with CD4 count >150/cmm, receiving DOTS alone). Control group comprised of 306 patients with TB alone, on DOTS. The age, gender distribution and socio-economic status were comparable among the groups. The distribution of sputum positive, sputum negative and extra-pulmonary cases among the groups is shown in [Table/Fig-1]. At the end of therapy, in study group, of the 7 patients in subgroup A, 2 patients died and 5 patients defaulted. All 30 patients in subgroup B improved were [Table/Fig-2]. Improvement was observed in all patients in control group.

### DISCUSSION

In our study, patients with concomitant TB and HIV who were simultaneously treated with DOTS and ART, showed poor outcomes. With the recent resurgence of tuberculosis in association

	Study group N (%)	Control group N (%)	Total N (%)	
Sputum positive TB cases	20 (12.0)	147(88.0)	167(100%)	
Sputum negative TB cases	11 (11.7)	83 (88.3)	94 (100%)	
Total Pulmonary TB cases	31(11.9)	230(88.1)	261(100%)	
Extra pulmonary TB cases	6 (7.3)	76 (92.7)	82 (100%)	
Total TB cases	37 (10.8)	306 (89.2)	343 (100%)	
[Table/Fig 1]: Distribution of type of tubercular disease among the study and control group				

Outcome	Subgroup A (n=7)	Subgroup B (n=30)		
Cases improved	-	30		
Cases died	2	_		
Cases not improved	5	_		
Total	7	30		
[Table/Fig 2]: Outcomes among the study subjects after completion of therapy				

with HIV, delivery of DOTS with ART has emerged as an unpredicted challenge. Several workers have tried different strategies for simultaneous delivery and improved compliance while on combined DOTS-ART treatment [2].

Increased risk of recurrence of TB had been reported while on ART-DOTS co-therapy [3]. Five of the 7 cases in our study were therapy defaulters by the time of final assessment. High incidence of adverse drug reactions to DOTS component may be one of the reasons behind this observation [4]. All of study subjects in subgroup B showed improvement, so did the control group subjects indicating the equivalent good efficacy of DOTS in the patients with and without HIV. The principle of DOTS remained same in patients with HIV infections with or without ART, though some workers recommend difference in intensity and frequency of DOTS however the 6 months DOTS therapy was considered adequate in both the settings [5].

With the prevalence of HIV with TB 69.48 per 1,00,000 of our population wascomparable to the prevalence from most of the

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Konaseema Institute of Medical Sciences, Amalapuram, AP, India. states in India. Hence, our observations are applicable to a wide population range across the India. However, our study is limited by small number of studied patients with DOTS-ART co-therapy. Inclusion of some sophisticated objective measure for assessment of patient response to treatment may provide a better insight into the issue.

# CONCLUSION

DOTS therapy given for 6 months is equally efficacious for tuberculosis in patients with and without HIV infection

DOTS-ART co-therapy may increase the incidence of adverse drug reactions and thereby the risk of therapy defaults by the patients

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None.

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