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## **Original Article**

## A study of adherence to DOTS regimen among pulmonary tuberculosis patients in West Tripura **District**

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#### ABSTRACT

Background: Noncompliance to the DOTS regimen leads to treatment failure, relapse, MDR tuberculosis, XDR tuberculosis etc. requiring more prolonged & expensive therapy.

Aim: To assess the adherence rate among pulmonary tuberculosis patients in west Tripura district and to study the factors affecting adherence to DOTS regimen among pulmonary tuberculosis patients.

Material and methods: This community based cross-sectional study was conducted among 220 pulmonary tuberculosis patients registered for treatment with DOTS therapy; under six randomly selected DMC of West Tripura District.

Results: The study revealed that the adherence rate among the pulmonary TB patients was 84.50 percent. Male tuberculosis patients had 87.10 percent less chance of being adherent to the DOTS regimen in reference to females, and Cat I patients were 8.96 times (C.I. 2.689 -29.857) more adherent to the therapy compared to the retreatment cases. Again, patients whose continuation phase was supervised as per the guidelines of DOTS were 12.07 times more adherent to the therapy. PTB patients who had the knowledge of supervised therapy in DOTS and curability of the disease, were 4.70 times (C.I. 1.39-15.79) and 9.39 times (C.I. 1.03-85.99) more adherent to the therapy, respectively.

Conclusion: The study showed good adherence to the regimen among pulmonary tuberculosis patients in spite of being a difficult area. It may also help in planning and implementation of tuberculosis control measures by addressing and overcoming the barriers regarding treatment completion.

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#### 1. Introduction

Tuberculosis (TB) remains a world-wide public health problem despite of the fact that the causative organism was discovered more than 100 years ago, and highly effective drugs and vaccines are available since decades making Tuberculosis a preventable and curable disease. As per the WHO Global TB Report 2012, there were an estimated 8.70 million incident cases of TB globally in 2011, out of which, 2.20 million were estimated to have occurred in India.

The treatment of tuberculosis as per RNTCP is through Directly Observed Treatment Short Course (DOTS) chemotherapy which is an internationally recommended strategy to ensure cure by providing the most effective medicine and confirming that it is taken. But poor adherence to the regimen is a major barrier to its global control. Studies conducted in different parts of India showed that 45 to 93 percent of tuberculosis patients are adherent to DOTS therapy.<sup>3-6</sup> Noncompliance to the treatment regimen leads to treatment failure, relapse, MDR tuberculosis, XDR tuberculosis etc. requiring more prolonged & expensive therapy. However, no studies have been conducted in West Tripura District assessing the adherence to DOTS regimen among the PTB patients registered under RNTCP. Hence, the present study was conducted to assess the adherence rate among pulmonary tuberculosis patients in West Tripura district and to study the factors affecting adherence to DOTS regimen among pulmonary tuberculosis patients.

#### 2. Material & methods

This was a Cross-sectional study conducted among Pulmonary TB patients registered under RNTCP in West Tripura District, Tripura. The district has 12 Designated Microscopic Centers (DMC), out of which six DMC was chosen by simple random sampling and the study was conducted among PTB patients registered for treatment, in all the 50 (fifty) DOT centers under the six selected designated microscopic centers. The study was conducted between November 2011 to October 2013.

Considering the adherence rate among pulmonary tuberculosis patients to be 66 percent, an allowance of error of 10 percent of the compliance, and the level of significance (or type 1 error) as 5 percent, the minimum required sample size for assessing the adherence of pulmonary tuberculosis patients to the DOTS regimen was calculated to be 198 using the formulae,  $\frac{Z_{0,2}^{2}pq}{p2}$ .

However, the present study included 220 PTB patients registered within July 2011 to June 2012in the six DMC under RNTCP, by systematic random sampling considering every second patient registered in the tuberculosis register maintained in each DMC.

The study included pulmonary tuberculosis patients who were≥15 years of age and registered for treatment with DOTS therapy at least 3 months before from the date of interview. Those patients who were transferred out or transferred into the DMC area, who did not gave consent for the interview and

who could not be traced to their homes in spite of making 2 home visits were excluded from the study.

Data was collected by interviewing the randomly selected pulmonary tuberculosis patients in their home, using a structured, pre-tested, interview schedule and treatment documents of the patients; after taking written informed consent from them.

Data analysis has been done in SPSS version 21 and Epi info version 7.0. Data were expressed in frequency, percentage and statistical analysis has been done using Pearson's chi square test, chi square test with Yates correction, Fisher exact test and multiple logistic regression analysis. P value of <0.05 was considered to be significant.

A patient was said to be adherent if the person takes appropriate drug regimen for required time. A patient was said to be non adherent or non compliant if the tuberculosis patient on DOTS therapy is Missing  $\geq 2$  consecutive weeks of DOTS, or there is prolongation of treatment for > 30 days due to sporadic missed doses. A patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment was said to have defaulted.

The study was sponsored by the Department of Biotechnology and was approved by the institutional ethics committee of Agartala Government Medical College.

#### 3. Results

The present study conducted among 220 pulmonary tuberculosis patients registered under RNTCP revealed that the adherence rate among the PTB patients of the West Tripura District was 84.50 per cent (Fig. 1), i.e., majority of the patients were taking the appropriate drug regimen for the required time.

Among the 15.50 percent noncompliant patients, 13.20 percent patients have either missed  $\geq$  two consecutive weeks of DOTS or had a prolongation of treatment by > 30 days due to sporadic missed doses, but they had not defaulted whereas, 2.30 per cent of the patients defaulted the treatment.

The socio demographic factors which were considered in the present study to affect treatment adherence included age, gender, religion, community, education, occupation and

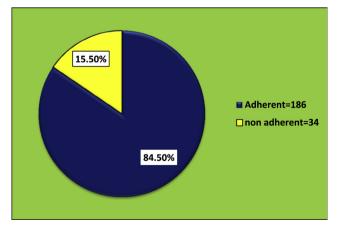


Fig. 1 – Pie chart showing distribution of patients according to their adherence to DOTS therapy.

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