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# Study of Various Causes of Treatment Interruption Among Tuberculosis Patients

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**Abstract:**

**Introduction:** India is the highest Tuberculosis (TB) burden country accounting for 1/5th (21%) i.e. 2 million cases of the global annual incidence of 9.4 million. Poor adherence to anti-tubercular treatment is a major barrier to disease control leading to defaulters.This study aimed to know the reasons of treatment interruption among the tuberculosis cases under Revised National Tuberculosis Programme (RNTCP) in Nagpur.

**Methods:** All the TB patients registered under RNTCP in Nagpur corporation which includes five tuberculosis units (TU) & two tertiary care centers, in one year, who interrupted treatment, were included in this study. Defaulter patientswere analyzed on basis of their records and cause for their treatment interruption was noted.

**Results:** Out of the total 2457 TB patients, 118 (4.8 %) defaulted. Reasons for treatment interruption were:migration - 30 (25.42%), alcoholism-17 (14.41%), unwillingness-18 (15.25%), side effects- 17 (14.41 %), shift of pathy 12 (10.17%), as asked by doctor/DOTS provider (medical reasons) in3(2.54%), work related reasons in 4 (3.39%)& pregnancy- 1 (0.85%).In 16(13.56 %) patients the cause was not recorded.

**Conclusion:** Migration was the most common cause of treatment interruption amongst the cases in our study followed by other causes like alcoholism, unwillingness, side effects, shift of pathy, medical reasons etc.

**Clinical implication:** The RNTCP needs to effectively address the reasons for treatment interruption right at the start of treatment and ensure effective check mechanisms during the course of treatment to avoid any potential treatment interruption. If we can decrease the proportion of patients interrupting treatment, then this may well help in improving the treatment outcomes under RNTCP.

Key words: Default, TB, Tuberculosis, Pulmonary tuberculosis, Defaulter

## Introduction:

India is the highest tuberculosis (TB) burden country in the world, accounting for approximately 20% of global incidence of TB.[1] Poor adherence to anti-tubercular treatment is a major barrier to disease control leading to defaulters. Understanding factors that can be targeted for improving adherence may improve overall treatment outcomes and thus help in achieving the goal of disease control. With this background, this study was conducted to know the reasons of treatment interruption among the tuberculosis cases under revised national tuberculosis programme (RNTCP), which is currently the

government sponsored TB control programme in India.

**Methods:**

This was a retrospective observational study. All the patients registered in one-year period from July 2015 to June 2016,under RNTCP in Nagpur corporation area which included five tuberculosis units (TU) along with two tertiary care centers and who interrupted treatment, were included in this study. The case definition used was as per RNTCP guidelines: Defaulterwas defined as "a patient who at any time after registration had not taken anti-TB drugs for 2 months or more consecutively." These patients included pulmonary TB (PTB) as well as extra-pulmonary TB (EPTB) cases who were new cases, previous defaulters, treatment failures or relapse patients. Patients were analyzed on the basis of their records and cause for their treatment interruption was noted.Proportion method of analysis was used with data entry in Microsoft excel software.

**Results:**

A total of 2457 TB patients were registered under RNTCP in Nagpur corporation area during the period of July 2015 to June 2016. Of these 118 (4.8%) patients (defaulted treatment. The profile depicting salient features of these defaulter patients is outlined in table no. 1. On further analysis, the various reasons for treatment interruption in these patients were: migration in 30 (25.42%) patients, alcoholism in 17 (14.41%) patients, unwillingness in 18 (15.25%) patients, side effects in 17 (14.41 %) patients, shift of pathy in 12 (10.17%) patients, as asked by doctor/DOTS provider (medical reasons) in3(2.54%) patients and work related reasons in 4 (3.39%) patients. 1 (0.85%) patient even defaulted as a result of pregnancy. In 16 (13.56 %) patients the cause was not recorded.The detailed graphical representationis depicted in figure no.1.

| Registered cases | 2457 |
|---|---|
| Defaulters | 118(4.8%) |
| Males | 91 (77%) |
| Females | 27(18%) |
| Human Immunodeficiency Virus infected (HIV +) | 8 (6.77%) |
| Extra pulmonary TB | 23(19.49%) |

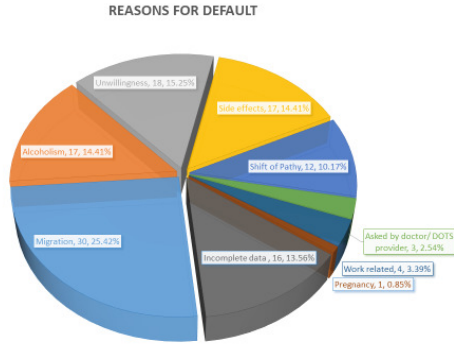**Table no.1 Salient features of defaulter patients.**

**Figure no. 1. Reasons for default of anti-TB treatment under RNTCP**

**Discussion:**

The present study highlights the problem of default during receiving anti-TB treatment under RNTCP, the state sponsored TB control programme in India. Migration (25.42 %) was the most common cause of treatment interruption amongst the cases in this study.This is in concordance with the previous study by K. Jaggarajamma et al. who showed that 24% defaulters in RNTCP, migrated.[2] The possible reasons for migration could be occupational, returning to the native place, domestic problems or other illnesses.

Alcoholism was the reason of default in 14.41 % of the patients. Basa et al. in their study had shown that majority of defaulter patients were alcoholics compared to non-defaulter patients.[3] This is a factor where intensive counselling at the start of treatment plays a very important role. Apart from default, alcoholics are at an increased risk of developing drug induced side effects also. Referral of such patients at the start of treatment for de-addiction could be a useful step.

Some patients in this study (15.25 %) showed unwillingness to continue further treatment. An initial symptomatic improvement or a non-response during therapy while on anti-tuberculosis therapy could be a major factor for this unwillingness. [3] 14.41 % of patients defaulted due to development of side-effects of which drug induced gastritis was the most common. In fact, a recent study by Bhadke et al. has shown anti-TB treatment induced side-effects as the leading cause of treatment interruption in RNTCP.[4]This factor needs to be considered in the overall programmatic context of RNTCP. A previous study has showed that 95.24% of prescriptions/ treatment cards in RNTCP have one or more anti-TB drug prescribed in overdoses.[1]This high proportion of overdosing of anti-tubercular drugs in RNTCP,is arisk factor for drug toxicity, intolerance and hence defaults due to such adverse effects of anti-tubercular drugs. A major reason for this is the absence of dosing weight bands in patients weighing more than 30 Kgs under the intermittent anti-TB regime in RNTCP. This can be explained from the fact that all the patients weighing more than 30 kg receive thesame 600 mg of Isoniazid (INH) thrice weekly under RNTCP. The current world health organization (WHO) guidelines recommend an INHdose of 10 mg/kg (8 to 12 mg/kg). According tothese guidelines the 600 mg dose of INH would be considered appropriate only for patients with weight >50 kg.[1,5,6] The newly proposed daily RNTCP regimes has provisions for weight bands above 30 kg which is a welcome step.

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Some patients (10.17 %) shifted to alternative pathies thus showcasing their lack of faith in the modern evidence based system of allopathy medicine. This is a cause of serious concern in India and needs to be addressed by counselling and stringent policy decisions.

A minimal proportion of patients (2.54 %) were shown as defaulter due to medical reasons. This can be exemplified from the fact that sometimes due to medical reasons the patient may have to be shifted on an alternate regime e.g. a hepatosafe regime or a weight based daily regime, which the patient tolerates better. For these patients there is no operational outcome other than default. An alternative outcome for these patients which truly reflects their disease conditions is the need of the day as these patients are merely following the medical advice offered to them. Work related factor was another minor factor seen in 3.39 % defaulter patients. 1 (0.85 %) patient even defaulted citing pregnancy as a reason. Any factor, however miniscule it may be, deserves attention for the overall success of a health programme.

In a significant proportion of patients (13.56 %) the records failed to show a cause of default. It may be mentioned here, that under RNTCP, the accountability of cure rests with the healthcare system and not the patient.[6]It is therefore imperative thatthe RNTCP pushes up its efforts to decrease the default rates. On careful analysis it can be inferred that most of the causes of default are preventable with aggressive initial counselling and patient education.

Decreasing the proportion of defaulters in RNTCP is very important. Defaulters are at risk of developing drug resistance. Any delay in diagnosing drug resistance in a patient can be catastrophic for the treatment outcome.[7]The problem of drug resistance is

a very big challenge for the RNTCP at present. Early identification of drug resistance in these patients is desirable. Also decreasing the proportion of defaulters in RNTCP is essential for improving the treatment outcomes of various RNTCP regimes, be it for drug sensitive or drug resistant TB.

Some of the ways in which the factors of default as shown in our study, can be addressed, are as follows. Counseling, education and motivation of all TB patients at treatment initiation is extremely important. Patient friendly health care services will be a good initiative. Currently under the 99 DOTS programme, a toll free number has been established which helps monitors each and every dose of anti-TB treatment.The health care providers need to be assigned a more proactive role. Allowing "DOTS supporters" to collect drugs for seriously ill patients is a positive possibility.[8] Involving family members and close people in the care of patients is another good idea. Awareness is required to be spread in society to stop discouraging or showing disrespectful behavior towards the TBpatients. Decentralization of services will help increase the reach of services to the last man standing in the queue. Schemes like NIKSHAY and 99 DOTS are a step forward in this direction.[9]Effective management and supplyof anti-TB drugs is a programmatic issue to be considered with all seriousness. Reducing frequency or duration of treatment through ongoing operational research will provide a major impetus to the RNTCP programme. Focus must be given on improving access and cost of TB treatment in our country. The Universal Access to Tuberculosis Care(UATBC)is a nice step in this regard.As part of UATBC, free anti-TB (ATT) drugs are provided to patients seeking healthcare from the private sector.[10] The patients complaining of side effects should be addressed with

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urgency. Addressing financial and psycho-social issues of the patients is a factor that can no longer be neglected. Making unannounced home visits by the health care worker is another step in checking the compliance of the patient. Incentives on completion of treatment is a policy decision which can be considered. Recently, TB has been made a notifiable disease in India. This will help trace the defaulter patients back on the health care map.

Our study thus highlights the various reasons for default by patients in RNTCP. The RNTCP needs to effectively address the reasons for treatment interruption right at the start of treatment and ensure effective check mechanisms during the course of treatment to avoid any potential treatment interruption. It requires a comprehensive approach. If we can decrease the proportion of patients interrupting treatment, then this may well help in improving the cure rates under RNTCP in times to come.

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