



Original Research Article

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## COMMONEST CAUSE OF INITIATING CATEGORY II DIRECTLY OBSERVED TREATMENT SHORT COURSE IN TUBERCULOSIS PATIENTS

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**ABSTRACT: Background:** Tuberculosis is a major public health problem in India. 330,000 Indians die annually of tuberculosis. Two out of every five Indians are infected with the TB bacillus. Very few studies have been carried out on finding out the commonest cause of initiating tuberculosis patients on Category-II DOTS. The present work was undertaken in Nerul, Navi Mumbai. **Methods:** A retrospective cross-sectional study was conducted in a treatment unit of Nerul, Navi Mumbai by analyzing randomly selected 100 treatment cards of Category-II DOTS patients of the years 2014 and 2015. A proforma was filled and the results were statistically evaluated. **Results:** Of the 100 patients initiated on Category-II DOTS, 44% were cases of Treatment After Default (TAD), 31% patients were cases of relapse, 18% others and 7% were failure cases. **Conclusions:** The study concluded that most patients on Category-II DOTS were Treatment after Default (TAD) cases. Of these, majority were sputum AFB positive pulmonary tuberculosis cases with a male predominance. Since patients on Category-II DOTS have already received anti-TB treatment earlier, they have higher chances of developing multi-drug resistant tuberculosis. So it is recommended that the reasons for default should be addressed and studied in greater detail.

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**KEYWORDS:** Default, relapse, failure, MDR-TB

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## 1. INTRODUCTION

Tuberculosis (TB) is a major public health problem in India. India accounts for one-fifth of the global TB burden. Each year nearly 2 million people in India develop TB, of which around 870,000 are infectious cases. It is estimated that annually around 330,000 Indians die due to TB i.e. two deaths every five minutes. Two out of every five Indians are infected with the TB bacillus<sup>1</sup>. Directly observed therapy short course (DOTS) is the internationally recommended strategy to ensure cure of tuberculosis; it has become the standard for the diagnosis, treatment and monitoring of tuberculosis worldwide and has been implemented in 182 of 211 countries, covering more than 77% of world's population in response to the growing threat of this disease. In India, The Revised National Tuberculosis Control Programme (RNTCP), based on the DOTS strategy, began as a pilot in 1993 and was launched as a national programme in 1997. RNTCP Phase II is expected to maintain at least 70% case detection rate of new smear positive and maintain a cure rate of at least 85%. Based on this; the treatment is divided into two categories, Category-I and Category-II. Category-II patients of sputum smear- positive pulmonary tuberculosis belong to 3 sub-groups. One sub-group is of relapse, second is of treatment failure and third one is of treatment after default. In rare and exceptional cases, patients who are sputum smear-negative or who have an extra-pulmonary disease can have relapse or failure. In these cases, the patient is categorized as 'Others' and given Category II treatment<sup>2</sup>. Most of the studies in India and abroad have addressed the outcome of Cat-II cases under RNTCP. Few studies have found the commonest cause of starting patients on Cat-II DOTS as part of their study on the outcome of Cat-II DOTS. One study determined that default was the commonest cause<sup>3</sup> & another study found that relapse was the commonest cause of starting patients on Cat-II DOTS<sup>4</sup>. We plan to conduct the above study to find out the commonest cause for initiating patient on Cat-II DOTS in TU-1 and TU-2 of Navi Mumbai Municipal Corporation. The aim of the study is to study the commonest cause for initiating tuberculosis patients on category II DOTS regime under RNTCP i.e. Relapse, Treatment after default, Treatment failure, Others.

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## 2. MATERIALS AND METHODS:

This was a cross-sectional, retrospective study with a simple random sampling of treatment cards of 100 patients receiving Category-II DOTS at TU-1 (Treatment Unit-1) of Nerul, Navi Mumbai in the years 2014 and 2015. TB register and treatment cards of Category-II patients taking treatment from TU-1 of Nerul, Navi Mumbai were used. The data was collected, tabulated and statistically analyzed. Since this was a retrospective study, WAIVER OF CONSENT was obtained from the institutional ethics committee (IEC). The Chi Square method was used for statistical analysis of the data.

Definitions:

**Relapse:-** A TB patient who was declared cured or treatment completed by a physician, but who reports back to the health service & is now found to be sputum smear positive.

**Treatment after default:-** A TB patient who receives anti-TB treatment for one month or more from any other source & returns to treatment after having defaulted i.e. not taken anti-TB drugs consecutively for 2 months or more & is found to be sputum smear positive.

**Failure: -** Any TB patient who is sputum smear positive at 5 months or more after starting treatment.

**Others:-** In rare and exceptional cases, patients who are sputum smear-negative or who have an extra-pulmonary disease can have relapse or failure. In these cases, the patient is categorized as 'Others' and given Category II treatment.

PROFORMA-

### Category-II DOTS commonest cause of initiation

Name:	Sex:	Age:
TB No.:	Occupation:	Contact No.:
Previous Category: DOTS	Pvt.AKT	
I      II		
Pulmonary ---SPUTUM AFB +VE	Extra-Pulmonary	
--- SPUTUM AFB -VE		

**Reason for initiating Category-II: Failure Default Relapse Others**

## 3. RESULTS AND DISCUSSION

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Randomly selected treatment cards of patients on Category-II from TU-1, Nerul, Navi Mumbai were analysed, The mean calculated age was 36.9 and most of the patients were in the age group of 20-49 years with a male predominance of 66%. Of the 100 patients studied, 85 % were pulmonary case and 72% were sputum AFB positive 21% of the sputum AFB positive patients were in the age group of 40-49.(table no.1)The commonest cause for initiating patients on Category-II DOTS was Treatment after Default i.e. TAD (44%). 31% patients were cases of relapse followed by others (18%) and 7% cases were of treatment failure. (Table 1) Of the 44 patients of TAD, 36 patients were sputum AFB positive with a male predominance and 8 were sputum AFB negative. (Table 2) Of the total, 65 patients were on DOTS under RNTCP and 35 patients received private AKT prior to initiating Cat-II DOTS. Of the 65 patients on DOTS, 57 were on Cat-I (88%), 8 on Cat-II (12%). Most of the patients initiated on Category II DOTS were sputum AFB positive pulmonary cases who had previously received Category I DOTS which was statistically highly significant. Tuberculosis is a major public health problem in India. Nearly 2 million people develop TB of which 870,000 are infectious<sup>1</sup>. A DOT is currently considered the best method to control tuberculosis globally. In India, RNTCP based on DOTS strategy has achieved 70% cure rate<sup>2</sup>. In our study of 100 patients initiated on Category-II DOTS, most were sputum AFB positive pulmonary cases which are a public health issue as they are infectious and lead to the spread of the disease. Default cases contribute to the same. Treatment after default was the commonest cause (44%) for initiating patients on Category-II DOTS. A study done by Sisodia et.al<sup>3</sup> also found TAD as the commonest cause, however the percentage was as high as 84.6%.

Patients generally default due to the following reasons:-

1. Migration to another place/change of residential address
2. Social stigma attached to tuberculosis
3. Alcoholism leading to reduced compliance
4. Drug toxicity & adverse reaction leading to avoidance of treatment
5. Socioeconomic and financial constrains.

As the patients defaulted on Category I or Pvt. AKT, the tendency to default on Category-II will also probably be high and these patients can develop MDR-TB and would require extended investigations and treatment which is a burden on the health system. Hence, the commonest cause for default should be studied and addressed. Since patients on Category-II DOTS have already received anti-TB

treatment earlier, they have higher chances of developing multi-drug resistant tuberculosis. We suggest that while initiating patients on DOTS treatment under RNTCP regime, the Medical Officer and TB health visitor should intensify counseling for patients who are alcoholic and who do not have permanent residential addresses as they tend to migrate and default. Studies to find the commonest cause of default and ways to address them should be conducted. Such studies will prevent default and hence reduce the burden on the health care system by reducing multi-drug resistant cases.

#### 4. CONCLUSION

From our study, we conclude that Treatment after Default (TAD) was the commonest cause of initiating patients on Category-II DOTS. Most of these were males who were pulmonary cases and sputum AFB positive. We recommend that the reasons for default should be addressed and studied in greater detail.

#### REFERENCES

1. WHO-Stop TB strategy. [Online] As accessed on URL: [www.who.int/tb/strategy/en/](http://www.who.int/tb/strategy/en/)
2. Revised National Tuberculosis Control Programme. [Online] As accessed on URL: [www.tbcindia.org/RNTCP.asp](http://www.tbcindia.org/RNTCP.asp)
3. Sisodia R.S,Wares,D.F.Sahu,Chauvan L.S,Zigonal M.;Source of retreatment cases under RNTCP in Rajasthan,India,2003,The international journal of tuberculosis &lung disease.No.12.Vol.10 Dec,2006:1373-1379
4. Mukherjee A,Sarkar A,Saha,Biswas B,Bhattacharya P.S. Outcome of different subgroup of smear positive retreatment patients under RNTCP in rural West Bengal India. Rural & remote health journal 2009 (source-internet): <http://www.rrh.org.au>
5. D.Behra,T.Balamugesh,Profile of treatment failure in tuberculosis experience from a tertiary care hospital.Lung India 2006;23:103-105
6. Connolly C,Davis GR,Wilkinson D.Who fails to complete tuberculosis treatment? Temporal trends 7 risk factors for treatment interruption in a community based directly observed therapy programme in a rural district of South Africa.Int J TB lung dis.1999;3:1081-1087
7. Crofton J failure in treatment of pulmonary tuberculosis potential causes & their avoidance.Bull IUAT 1980; 55:93-99
8. Teklu B. Reasons for failure in treatment of pulmonary tuberculosis in Ethiopian Tubercle 1984; 15:17-21

**Table No 1. Cause for initiating Category-II**

Cause for initiating Cat-II	Frequency	Percentage (%)
Failure	7	7.0
Default	44	44.0
Relapse	31	31.0
Others	18	18.0
Total	100	100.0

**Table No. 2: Sputum status vs Cause vs Sex.**

SPUTUM	Cause for initiating Cat-II	SEX		
		Female	Male	
Negative	Failure	1	0	1
	Default	4	4	8
	Relapse	1	2	3
	Others	7	9	16
	Total	13	15	28
Positive	Failure	2	4	6
	Default	8	28	
	Relapse	10	18	
	Others	1	1	2
	Total	21	51	72