# Treatment Outcome Among the Retreatment Tuberculosis (TB) Patients under RNTCP in Chandigarh, India

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#### **ABSTRACT**

**Background:** 'RETREATMENT' for Tuberculosis (TB) has long been a neglected area in global TB control. While other components of the Stop TB Strategy have garnered appropriate focus and, increasingly, sufficient resources, issues related to the TB of patients previously treated for tuberculosis remain under examined and under-resourced.

**Methods:** A longitudinal study was designed and the patients registered under Revised National Tuberculosis Control Programme (RNTCP) category II from June 2010 to December 2011.Out of total 607 patients registered during this period under category II of RNTCP in Chandigarh (India), 545 consented to participate in the study. These were followed up to September 2012 till the completion of treatment.

**Statistical Analysis:** The analysis was done by using SPPS-18 statistical software package. Chi- square test was used for testing association of different characteristics. **Results:** Four Hundred Thirty (78.9%) of the patients had pulmonary TB and 115(21.1%) of the patients had extra pulmonary TB. In the study cohort of category II patients 264(48.4%) were relapse patients,167(30.6%) belonged to others category, 75(13.8%) were on treatment after default, 39(7.2%) were failure cases. The mean age of patients was  $35.92\pm15.42$  (p = 0.928). Maximum patients belonged to age group of 25-34 years (25.3%). Seventy Three (13.4%) were Illiterate. In treatment after default group only 65.3% patients were cured. Maximum deaths 8% were seen in treatment after default group of patients. The overall default in the study was 5.9%.

**Conclusion:** The findings of this study suggest that it is essential to monitor re-treatment patients with same vigour to reduce default and improve their treatment outcome.

## **INTRODUCTION**

After successfully pilot testing the RNTCP in a population of 2.35 million it was extended to a population of 13.85 million in 1995 and 20 million in 1996, to assess its operational feasibility [1]. The program is covering the entire nation since March 2006 reaching over a billion population. By October 2012, the number of RNTCP District Units stands at 662 with 2,698 functional sub-district TB Units for effective & decentralized supervision and over 13,000 Designated Microscopy Centers for quality sputum microscopy for diagnosis of TB [2].

There were an estimated 8.8 million incident cases of TB (range, 8.5 million–9.2 million) globally in 2010 equivalent to 128 cases per 100,000 population. Most of the estimated number of cases in 2010 occurred in Asia (59%) and Africa (26%). There were an estimated 12.0 million prevalent cases (range, 11.0 million–14.0 million) of TB in 2010. This is equivalent to 178 cases per 100,000 population [2].

'RETREATMENT' for TB has long been a neglected area in global TB control. While other components of the Stop TB Strategy have garnered appropriate focus and, increasingly, sufficient resources, issues related to the treatment of patients previously treated for TB remain under-examined and under-resourced [3].

While global reporting on overall retreatment outcomes appears acceptable, with a treatment success rate of 70%, important geographical and sub-category differences likely exist. Yet, the evidence base to guide policy on TB retreatment remains shallow [4].

It is to be realized that even after achieving 70% case detection and 85% cure rate, we are actually curing 59% patients. What about the remaining 41% of the cases in the community? By curing only 59% of patients, the goal of RNTCP cannot be achieved [5].

Keywords: Tuberculosis, Default, Retreatment, RNTCP

It is imperative to identify the important reasons of default and appropriately retrieve the patients who interrupt the treatment. The present study aims at studying the treatment outcomes of different subcategories of patients recruited under category II of RNTCP, Chandigarh.

#### MATERIALS AND METHODS

Chandigarh, a Union Territory is also the capital of Punjab and Haryana situated in the northern part of the India.

RNTCP was launched in Chandigarh on 25th January 2002. RNTCP is implemented in the UT through District Tuberculosis Center (DTC) located in Sector 34. DTC There are three Tuberculosis Units (TUs). TU I is located at sector 22 Polyclinic, while TU II is located at sector 45 Polyclinic and TU III is located at Community Health Centre (CHC), Manimajra. Microscopic centers have been linked with these TUs.

A longitudinal study was designed and the patients registered under RNTCP category II from June 2010 to December 2011 at various centers in Chandigarh formed the study cohort. Out of total 607 patients registered during this period under category II of RNTCP in Chandigarh, 545 consented to participate in the study. These were followed upto September 2012 till the completion of treatment. Both pulmonary and extra-pulmonary were enrolled, irrespective of the sputum status. Patients of category I, transferred out, transferred in during the period were excluded from the study. Informed consent was taken from the respondents (or guardians in case of minors) and ethical guidelines under Declaration of Helsinki were followed. Institutional Ethical Committee also approved the study.

From the cohort of 545 patients enrolled in the study, information regarding their socio demographic profile, educational and

occupation status was obtained. Besides they were classified according to the disease classification, i.e., Pulmonary/Extra pulmonary.

#### **STATISTICAL ANALYSIS**

Statistical analysis was carried out using various statistical tests. Normal test of proportions was used for testing significance of difference between proportions. Chi-square test was used for testing association of different characteristics. The analysis was done by using SPPS-18 statistical software package.

## RESULTS

Four Hundred Thirty (78.9%) of the patients had pulmonary TB and 115(21.1%) of the patients had extra pulmonary TB. In the study cohort of category II patients 264(48.4%) were relapse patients, 167(30.6%) belonged to others category, 75(13.8%) were on treatment after default, 39(7.2%) were failure cases.

The study included 348(63.9%) males and 197(36.1%) female patients registered under category II of RNTCP, Chandigarh (India). Among the males 169(48.5%) were relapse cases, 62(17.8%) were

treatment after default. Among the females 79(40.1%) belonged to others category while 95(48.2%) were relapse cases.

The mean age of patients was  $35.92\pm15.42$  (p = 0.928). Maximum patients belonged to age group of 25-34 years (25.3%). In this group 64(44.2%) were relapse patients, while 49(35.5%) belonged to others category. Maximum treatment after default patients 20(17.7%) were observed in the age group of 35-44 years.

Eighty (52.3%) patients were single and relapse patients while 48(31.4%) were single and belonged to others category.172 (46.9%) were married and relapse patients while 31(8.4%) were failure cases [Table/Fig-1].

Maximum patients were in service 149(27.3%), followed by housewives 109 (20%), 95(17.4%) were labourers.

In the present study 73(13.4%) of the patients were Illiterate, followed by 150 (27.5%) went to middle school while 111(20.4%) did primary schooling [Table/Fig-1].

Cure rate was maximum (77.7%) in the patients belonging to the relapse category. A default rate of 12.8% was observed from the patients belonging to the failure category. In treatment after default

	Relapse	Failure	Treatment after Default	Other	Total (%)					
Age										
5-14(%)	4(40)	O(O)	O(0)	6(60)	10(1.8)	Chi-square:22.73				
15-24(%)	66(51.6)	10(7.8)	17(13.3)	35(27.3)	128(23.4)	p value:0.826				
25-34(%)	64(46.3)	8(5.8)	17(12.3)	49(35.5)	138(25.3)					
35-44(%)	60(53.1)	8(7.1)	20(17.7)	25(22.1)	113(20.7)					
45-54(%)	35(47.9)	6(8.2)	11(15.1)	21(28.8)	73(13.4)					
55-64(%)	23(41.8)	5(9.1)	6(10.9)	21(38.2)	55(10.1)					
>64(%)	12(42.9)	2(7.1)	4(14.3)	10(35.7)	28(5.1)					
Sex										
Male (%)	169(48.5)	29(8.3)	62(17.8)	88(25.3)	348(63.9)	Chi-square:23.1 p value:.001				
Female (%)	95(48.2)	10(5.1)	13(6.6)	79(40.1)	197(36.1)					
Religion										
Hindu (%)	220(47.4)	27(5.8)	69(14.9)	148(31.9)	464(85.1)	Chi-square:26.9				
Sikh (%)	27(58.7)	5(10.9)	3(6.5)	11(23.9)	46(8.4)	p value:0.029				
Muslim (%)	16(50)	6(18.8)	8(25)	2(6.5)	32(5.9)					
Christian (%)	1(33.3)	1(33.3)	1(33.3)	O(O)	3(0.5)					
Marital Status										
Single (%)	80(52.3)	7(4.6)	18(11.8)	48(31.4)	153(28.1)	Chi-square:5.2				
Married (%)	172(46.9)	31(8.4)	54(14.7)	110(30)	367(67.3)	p value:0.877				
Widow/Widower	12(48)	1(4)	3(12)	9(36)	25(4.6)					
Occupation										
Service (%)	78(52.4)	11(7.4)	23(15.4)	37(24.8)	149(27.3)	Chi-square:41.01				
Business (%)	26(41.1)	7(11.1)	14(22.2)	16(25.4)	63(11.5)	p value:0.224				
Agriculture (%)	2(40)	1(20)	O(O)	2(40)	5(0.9)					
Retired (%)	10(71.4)	O(O)	2(14.3)	2(14.3)	14(2.5)	_				
Student (%)	26(49.1)	3(5.7)	3(5.7)	21(39.6)	53(9.7)					
Housewife (%)	52(47.7)	5(4.6)	7(6.4)	45(41.3)	109(20)					
Labourer (%)	42(44.3)	9(9.5)	18(18.9)	26(27.4)	95(17.4)					
Others (%)	28(49.1)	3(5.3)	8(14)	18(31.6)	57(10.5)					
Education										
Illiterate (%)	39(53.4)	6(8.2)	9(12.3)	19(26)	73(13.4)	Chi-square:30.77				
Primary (%)	65(43.3)	11(7.3)	28(18.7)	46(30.7)	150(27.5)	p value:0.427				
Middle (%)	44(39.6)	11(9.9)	18(16.2)	38(34.4)	111(20.4)					
High (%)	57(53.7)	6(5.7)	14(13.2)	29(27.4)	106(19.5)					
Secondary (%)	34(56.6)	4(6.7)	4(6.7)	18(30)	60(11)					
Graduate (%)	23(56.1)	1(2.4)	2(4.9)	15(36.6)	41(7.5)					
Post Graduate (%)	2(50)	O(O)	O(0)	2(50)	4(0.7)					
[Table/Fig-1]: Socio-de	mographic profile with typ	pe of patients								

	Treatment Outcome								
Type of patient	Cure	Treatment Complete	Failure	Default	Died during Treatment	Total (%)			
Relapse (%)	205(77.7)	8(3)	23(8.7)	16(6.1)	12(4.5)	264(48.4)			
Failure (%)	18(46.2)	3(7.7)	12(30.6)	5(12.8)	1(2.6)	39(7.1)			
Treatment after Default (%)	49(65.3)	1(1.3)	10(13.3)	9(12)	6(8)	75(13.8)			
Other (%)	11(6.6)	149(89.2)	1(0.6)	2(1.2)	4(2.4)	167(30.7)			
Total (%)	283(51.9)	161(29.5)	46(8.4)	32(5.9)	23(4.3)	545(100)			
[Table/Fig-2]: Treatment outcomes by the type of the patients									

only 65.3% patients were cured. In the patients categorised as treatment after default 8% deaths were observed which was highest among all the group of the patients [Table/Fig-2].

The overall default in the study was 5.9%, while failure rate was 8.4%. 4.3% of the patients died during the course of the treatment.

## DISCUSSION

In the present study on the retreatment patients maximum patients belonged to the age group of 25-34 years(25.3%). The mean age of patients was  $35\pm15.4$ . In an earlier study conducted at Chandigarh by Kaur G et al., the mean age of the patients in category II was  $31.7\pm10.1$  years [6].

Males 348(63.9%) out numbered females 197(36.1%) in this study with Male to Female ratio of 1.76:1. Similar trends have been observed by Jha UM et al., with 1198(70%) males and 514(30%) females in the study on retreatment TB cases [7].

In the present study 67.3% (367) patients were married, while Sophia V et al., reported 59.4% married TB patients in a study conducted at Bangalore, India [8].

In the present study 13.4% patients were illiterate which is much lower than observed in studies done by Vats M et al., [9] and Sophia V et al., [8] who have reported 43% and 29.2% illiterate patients in their studies carried out at Ajmer and Bangalore respectively. This could be attributed due to better infrastructure and education facilities available at Chandigarh being a union territory and capital of two states, Punjab and Haryana, India.

Most of the patients were Hindus (85.1%) which is higher than the overall population of Hindus in the census. However there is no predilection of TB towards any religion.

In the present study cohort of category II patients 48.4% were relapse patients, 30.6% belonged to others category, 13.8% were on treatment after default, 7.2% were failure cases while in a study done by Jha UM et al., 33.0% were relapse patients, 37.6% were treatment after default, 20.5% were other patients, and 8.9% were failure cases [7].

Cure rate was highest in the relapse group (77.7%) while in the failure group was 46.2%. Treatment completion rate was highest (89.2%) in the Other group of patients. This may be attributed to the fact that most patients are registered as sputum negative in this subgroup.

Failure rate was highest in the subcategory of failure patients (30.6%). There is a need to investigate the reasons for high failure rate in this subgroup of the patients.

The successful completion of treatment was seen in 81.4% patients in the present study which is higher than average 70.8% of whole India [10]. The failure rate in present study was 8.4% which is lower than reported by earlier authors from Delhi (13%) [11].

The death rate in the present study was 4.2%. Earlier authors have reported a much higher death rate than reported in the present study. This finding does not agree with the present study [10-13].

The overall default in the study was 5.9% which is far lower than the average 14.3% of the whole of India [10].

RNTCP as a policy emphasizes on the new smear positive patients

and their treatment outcome. The findings of this study suggest that it is essential to monitor re-treatment patients with same vigour to reduce default and improve their treatment outcome. The findings of the study also suggest that RNTCP is running successfully in UT Chandigarh in the retreatment groups, having high success rate and low default rate compared to the national averages and there is an urgent need of sustaining this success.

# LIMITATIONS

This study is from patients who were registered for treatment under RNTCP. A large number of TB patients in India are treated outside the programmatic setting [14].

Further there is no information on the magnitude of TB patients who prefer to be retreated from the RNTCP or a different source (Private practitioners, Hospitals, Ayurvedic practitioners, Other Medicinal systems, Quacks, etc.). Due to long duration of therapy, psychological and other associated factors with therapy patients may opt for trying some alternative therapy/system.

Due to different systems of medicine prevalent in the country the past treatment profile of retreatment may also be affected by the type of health service provider used by the patient and the reach of RNTCP to the different health service providers.

Further TB in retreatment groups affects the quality of life of these patients which could have a bearing on treatment outcomes and was not assessed in the present study.

# CONCLUSION

The findings of the study also suggest that RNTCP is running successfully in UT Chandigarh in the retreatment groups, having high success rate and low default rate compared to the national averages. The findings of the study may be used in future researches to compare default rates in different parts of the country and to assess the reasons for default that may be observed in different settings.

Future researchers should also focus on assessing the quality of life of these patients which could affect treatment outcome.

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#### REFRENCES

- [1] Chauhan LS. Challenges for RNTCP in India. JIMA. 2003; 101(3):152-3.
- [2] Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi. The future of DOTS expansion in India. (Accessed on 2012 Nov 12) Available from URL:http://tbcindia.nic.in/ impRNTCP.html
- [3] Rusen ID. Tuberculosis retreatment: a topic whose time has come. Int J Tuberc Lung Dis. 2009; 10(13):1192.
- [4] World Health Organization Geneva, Switzerland. Global tuberculosis control: epidemiology, strategy, financing. WHO report; 2009:411-12.
- [5] Mittal C, Gupta SC. Noncompliance to DOTS. How can it be decreased. 2010; Indian J Community Med. 2011; 36(1): 27–30.
- [6] Kaur G, Goel NK, Kumar D, Janmeja AK, Swami HM, Kalia M.Treatment outcome of patients placed on treatment under directly observed therapy short course. *Lung India*. 2008 Apr-Jun; 25(2): 75–7.

- [7] Jha UM, Satyanarayana S, Dewan PK, Chadha S, Wares F, et al. Risk factors for treatment default among re-treatment tuberculosis patients in India, 2006. *PLoS ONE*. 2010; 5(1): e8873. doi:10.1371/journal.pone.0008873.
- [8] Sophia V, Balasangameshwara VH, Jagannatha PS, Saroja VN, Kumar P. Treatment outcome and two and half year follow up of new smear positive patients under RNTCP. *Indian J Tuberc.* 2004;51:199-208.
- [9] Vats M, Gupta RC, Gupta RL, Dadhich P, Vats D, Taylor M. Defaults under revised national TB control program: a prospective analysis of 300 patients on DOTS. *Chest.* 2003:212-14.
- [10] Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi. TB India 2012, *RNTCP Status Report*; 2012:7-17.
- [11] Bhat S, Sarin R, Jaiswal A, Chaudhary A, Singla N, Mukherjee S. Revised national tuberculosis control programme: an urban experience. *Indian J Tuberc*. 1998:45:207-10.
- [12] Srivastva SK, Ratan RK, Srivastva P, Parsad R. Report on revised national tuberculosis control programme-urban pilot project in Lucknow. *Indian J Tuber*. 2000; 47(3):159-61.
- [13] Dholakia Y, Danani U, Desai C. Relapse following Directly Observed Therapy Short Course (DOTS)-a follow up study. *Indian J Tuberc.* 2000; 47:233-36.
- [14] Sachdeva KS, Satyanarayana S, Dewan PK, Nair SA, Reddy R, Kundu D, et al. Source of previous treatment for re-treatment TB cases registered under the national TB control programme, India, 2010. PLoS ONE. 2011; 6(7): e22061.

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