



DEFAULTERS OF DIRECTLY OBSERVED TREATMENT SHORT COURSE (DOTS): EXTENT AND ASSOCIATED SOCIODEMOGRAPHIC FACTORS

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ABSTRACT

Introduction: India is a country with the highest burden of TB. Poor patient adherence to the treatment regimen is a major cause of treatment failure and of the emergence of drug-resistant TB.

Aims and Objectives: to determine the extent of non-adherence (defaulter rate) and various socioeconomic factors associated with non-adherence of DOTS treatment.

Material and Methods: Observational type of descriptive study was conducted at Akola TU. All tuberculosis patients registered and treated during the period of last four years with (DOTS) regimen were included under study. Data was obtained from tuberculosis (TB) register maintained at TU.

Observation: 212 (11.01%) out of 1926 TB patients who were put on DOTS regimen defaulted the treatment. Male gender, higher age, pulmonary type of disease and previous TB treatment were found to be significantly associated with the likelihood of nonadherence to the treatment under DOTS.

KEYWORDS : Tuberculosis, Defaulter, DOTS, RNTCP

Introduction

India is a country with the highest burden of TB. The World Health Organization (WHO) TB statistics for India for 2015 give an estimated incidence figure of 2.2 million cases of TB for India out of a global incidence of 9.6 million. The estimated TB prevalence figure for 2015 is given as 2.5 million.¹

The Revised national Tuberculosis control program (RNTCP) thus formulated was internationally recommended and adopted in 1993. Directly observed Treatment short course (DOTS) strategy is the most systematic and cost effective approach to revitalize 19 TB control Program in India with the goal of achieving 70% detection of new cases and cure rate of 85% of the cases.²

The large scale implementation of the Indian government's Revised National TB Control Program (RNTCP) was started in 1997. The RNTCP was then expanded across India until the entire nation was covered by the RNTCP in March 2006.³ The RNTCP has resulted in impressive improvements in cure rates and substantial decline in death rates with low rates of default.⁴

Poor patient adherence to the treatment regimen is a major cause of treatment failure and of the emergence of drug-resistant TB. Patient adherence to the standard anti-TB therapy in developing countries has been estimated to be as low as 40%.⁵

One major obstacle to the control of TB is failure to complete the lengthy treatment of 6 or more months. Treatment default is defined by the World Health Organization (WHO) as treatment interruption of at least two months.^{6,7}

The therapeutic regimens given under direct observation as recommended by WHO have been shown to be highly effective for both preventing and treating TB but poor adherence to anti tuberculosis medication is a major barrier to its global control.^{8,9} The public health and clinical consequences of TB treatment default are severe. Relative to those who complete treatment, patients who default may perpetuate TB transmission and have high post-treatment mortality and rates of recurrent disease.^{10,11}

Present study was conducted to determine the extent of non-adherence and various socioeconomic factors associated with non-adherence of DOTS treatment.

Material and Methods

Observational type of descriptive study was conducted at Vasantrao Naik Govt. Medical College, Yavatmal, Maharashtra. Out of total three tuberculosis units (TUs) in Akola district, one namely Akola TU was selected randomly. All tuberculosis patients registered and treated

during the period of last four years i.e. from 01/01/2011 to 31/12/2014 with direct observational treatment short course (DOTS) regimen were included under study. Data was obtained from tuberculosis (TB) register maintained at Akola TU. Data was analyzed with SPSS and epi-info software. Permission from institutional ethical committee was obtained before beginning of the study. Privacy and confidentiality of the data was strictly maintained.

Under DOTS, all confirmed TB patients are divided into new patients and previously treated patients. New patients are treated under Cat I regimen [2(HRZE)₃ + 4(HR)₃] and previously treated patients are treated under Cat II regimen [2(HRZE)₃ + 1(HRZE)₃ + 5(HR)₃]. All anti tubercular drugs namely Isoniazid (H), Rifampicin(R), Pyrazinamide (Z), Ethambutol (E) and Streptomycin(S) are given on an alternate day basis. Previously treated patients include failure, defaulter and relapse patients.

Patients put on DOTS can have one of the treatment outcomes namely cured, treatment completed, transferred out, switched to category IV, failure and defaulter.

Defaulter is a patient who left DOTS treatment for at least two months.

Present study was conducted to determine the extent of non-adherence and various socioeconomic factors associated with non-adherence of DOTS treatment.

Observations

There were total 1926 TB patients registered and treated under DOTS at Akola TU. Out of these 1714 (88.99%) patients adhered to the treatment regimen and remaining 212 (11.01%) were defaulter. [Table No.1]

Table No. 1 Distribution according to Treatment Outcome

Treatment Outcome	No	%
Cured	720	37.38
Treatment Completed	680	35.31
Died	175	09.09
Defaulter	212	11.01
Failure	110	05.71
Transferred Out	18	0.93
Switched to Category IV	11	0.57
Total	1926	100.0

During the year 2011, 2012, 2013 and 2014, 71, 47, 39 and 54 patients were defaulter out of total 559,485, 455 and 432 total patients treated respectively.

Genderwise distribution revealed significantly more male patients (12.82%) defaulted treatment than female (7.36%) patients.

More than half (%) of the defaulters belonged to the productive age group i.e. 30-45 years followed by another one third (%) in the age group of 15-30 years. Proportion of the defaulter patients went on increasing as age increased. Lowest proportion (0.91%) was found among the age group of 0-15years while it was highest among the age group of more than 75 years.

No significant difference was observed regarding non adherence to the

Table No. 2 Factors associated with defaulter

	Defaulter		Non Defaulter		Total		
	No. (n=212)	% (n=11.01%)	No (n=1714)	% (n=88.99)	No (n=1926)	% (n=100)	
Yearwise Distribution							
2011	71	33.49	488	87.29	559	29.02	$\chi^2 = 6.324$ df = 3 p>0.05
2012	47	09.69	438	90.30	485	25.18	
2013	39	08.67	411	91.33	450	23.36	
2014	55	12.73	377	87.26	432	22.43	
Genderwise Distribution							
Male	165	12.82	1122	87.18	1287	66.82	$\chi^2 = 13.02$ p<0.05
Female	47	07.36	592	92.64	639	33.18	
Age wise Distribution							
0-15	1	0.91	109	99.09	110	5.71	$\chi^2 = 13.26$ df = 5 p<0.05
16-30	71	11.16	565	88.84	636	33.02	
31-45	69	11.79	516	88.21	585	30.37	
46-60	40	10.99	324	89.01	364	18.90	
61-75	29	13.30	189	86.70	218	11.32	
>75	02	15.38	11	84.62	13	0.67	
HIV Status wise Distribution							
Positive	12	09.67	111	90.24	123	06.39	$\chi^2 = 0.0264$ p>0.05
Negative	138	09.31	1344	90.69	1482	76.95	
Unknown	62	19.31	259	80.69	321	16.67	
Distribution according to Type of Disease							
Pulmonary	181	12.19	1304	87.81	1485	77.10	$\chi^2 = 9.239$ p<0.05
Extra pulmonary	31	07.03	410	92.97	441	22.90	
Distribution according to Previous Treatment							
New (CAT I & III)	135	09.13	1343	90.87	1478	76.74	$\chi^2 = 17.58$ p<0.05
Previously Treated (CAT II)	77	17.19	371	82.81	448	23.26	

Among the previously treated (CAT II) patients, comparatively more (36.05%) patients those who were defaulter at the beginning of the treatment were non adherent to the treatment than those who were failure (17.78%) and relapse (12.50%) the beginning.

Table No.3 Distribution of Previously Treated Patients

	Defaulter		Non Defaulter		Total	
	No.	%	No	%	%	No
Failure	08	17.78	37	82.22	45	10.59
Relapse	21	12.50	147	87.50	168	39.53
Defaulter	31	36.05	55	63.95	86	20.24
Others	17	13.49	109	86.51	126	29.65
Total	77	18.12	348	81.88	425	100.00

Discussion

The present study was conducted to determine the extent of non-adherence and various socioeconomic factors associated with non-adherence of DOTS treatment.

There were total 1926 patients treated with DOTS regimen under RNTCP at Akola TU from 01/01/2011 to 31/12/2014. Out of these 720(37.38%), 680(35.31%), 212(11.01%), 175 (9.09%), 110(5.71%), 18(0.93% and 11(0.57%) had cured, treatment completed, defaulter, died, failure, transferred out, switched to category IV outcome respectively as per RNTCP definitions.212 (11.01%) patients who were defaulter studied for their socioeconomic determinants. The defaulter rate observed was very high, almost double, than that recorded at national level (6%) and also at Aligarh, UP(6%)¹² and at Yavatmal, Maharashtra (7.7%). But it was less than that observed at Paschim Medinapur district of West Bengal (14.1%)¹³.

Defaulter rate was the highest (33.49%) in the year 2009 followed by 12.73 % in 2012, 8.67% in 2011 and 9.69%. This difference was

treatment among HIV positive (9.76%) and HIV negative (9.31%) patients.

Compared to the extrapulmonary TB patients (7.03%), significantly more pulmonary TB patients (12.19%) were non adherent to the DOTS regimen.

Defaulters were less (9.13%) among the new (CAT I and III) patients (9.13%) than among the previously treated (CAT II) patients (17.19%). This difference was found to be statistically significant.

statistically not significant. Similar trend was also observed in concerned years by joint monitoring mission (JMM).¹⁴

Genderwise distribution revealed significantly more male patients (12.82%) defaulted treatment than female (7.36%) patients. Similarly significant higher non adherence among male patients than females was also observed by Suparna Bagchi et al¹⁵, Ugra Mohan Jha et al¹⁶ and Sarangi SS al¹³. The higher rate of default in men compared to women can be assumed to their role of being the earning member in the family.

Proportion of the defaulter patients went on increasing as age group increased. Lowest proportion (0.91%) was found among the age group of 0-15 years while it was the highest (15.38%) among the age group of more than 75 years. This difference was found statistically significant (p<0.05). In accordance with the present study findings, Bernard N Muture et al¹⁷ also observed that young adults and the elderly were at a higher risk of defaulting compared to children. Similarly Imad Cherkauoui et al¹⁸ also revealed that Age above 50 years was a significant independent risk factor for likelihood of treatment default. No significant difference was observed regarding non adherence to the treatment among HIV positive (9.76%) and HIV negative (9.31%) patients. These findings are similar to that of study by Gebreslassie Gebremariam, et al¹⁹, but are contradictory to that of study by Bernard N Muture, et al¹⁷ in which HIV positivity was found a significant independent risk factor for likelihood of treatment default.

Compared to the extrapulmonary TB patients (7.03%), significantly more pulmonary TB patients (12.19%) were non adherent to the DOTS regimen. Comparable results were recorded by the studies carried out in Tamilnadu²⁰ and Goa²¹.

Treatment adherence was better among the new (CAT I and III) patients (9.13%) than that among the previously treated (CAT II) patients (17.19%). This difference was found to be statistically

significant. Recent annual status report of RNTCP India has also revealed somewhat lower but significantly different similar defaulter rates among new (4%) and previously treated (11%-14%) TB patients. Similar significant difference was also observed in India²⁰ as well as abroad¹⁸.

Among the previously treated (CAT II) patients, comparatively more (36.05%) patients those who were defaulter at the beginning of the treatment were non adherent to the treatment than those who were failure (17.78%) and relapse (12.50%) the beginning. Similarly history of previous default was observed as independent risk factor for default by Bernard N Muture et al.¹⁷ Also Ugra Mohan Jha et al¹⁶ reported that patients who defaulted were more likely to have been initially classified as “treatment after default” registration type.

Conclusion

212 (11.01%) out of 1926 TB patients who were put on DOTS regimen defaulted the treatment. Male gender, higher age, pulmonary type of disease and previous TB treatment were found to be significantly associated with the likelihood of nonadherence to the treatment under DOTS.

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