



Effect of Disease Related Variables on Treatment Outcome Under DOTS

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Abstract

The study was undertaken to assess the effect of various disease related variables on treatment outcome of patients treated under Directly Observed Treatment Shortcourse (DOTS) chemotherapy. The objective of the study is to identify the factors which affect treatment outcome and are responsible for default. This Cross sectional study was carried out at three TUs (Tuberculosis Unit) of Agra city, Uttar Pradesh, India. Two DMCs (designated microscopy centers) were selected randomly from each TU. All the patients from the DOTS centers under these DMCs registered during January to December 2007 were included in the study until the sample size of 900 patients was complete. Treatment cards of these patients were obtained from their respective DMCs after their outcome had been recorded. Chi-square test was used for statistical analysis. 71.6% patients had favorable outcome while 15.1% defaulted. Defaulter were more among category-II (26.4%), pulmonary cases (18.2%) and retreatment cases (28.4% among treatment after default, 18.8% among failure and 42.9% among relapse cases), while 19.4% & 18.3% of patients among sputum positive & negative patients defaulted. Deaths were also more among pulmonary (8.0%), category II (12.3%) & treatment after default cases (11%). Favorable outcome was observed among 80.4% of new patients, 72.8% of category I patients and 85.7% of category III patients. 83.5% of patients with extra pulmonary disease had favorable outcome, while only 67.4% of pulmonary TB patients had favorable outcome. Present study concludes that default to treatment is more among category II patients, retreatment cases and patients with pulmonary disease.

Key Words

Tuberculosis, Directly Observed Treatment, Shortcourse, default

Introduction

Directly Observed Treatment 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 183 out of 211 countries, covering more than 83% of world's population (1). At national level the programme has nearly achieved its twin objectives of case detection and cure rates (new sputum smear positive cases) during the second quarter 2007 (2). During first quarter 2008, a total of 3,68,969 patients were registered for treatment and success rate of treatment was found to be 86.1% among new smear positive cases, 86.8% among new smear negative cases and 91.2% among new extra pulmonary cases (3). If we observe treatment outcome of new patients over past few years, both smear positive and smear negative patients are showing a trend of increased non-compliance

to treatment, as 6.7 % smear positive and 8.3% smear negative patient defaulted in 2007 as compared to 5.9% and 6.6% patients respectively in 2004 (4). Further, it is to be realized that even after achieving a case finding rate of 70% and cure rate of 85%, of the 100 patients of tuberculosis in the community we are actually curing 59 patients. What about the remaining 41% of the cases in the community? These patients may act as a source of infection for the community and even give rise to emergence of drug resistant tuberculosis. We are aiming at minimizing the proportion of retreatment cases among patients kept on DOTS by achieving higher cure and treatment completion rate. A number of factors are responsible for affecting the treatment outcome of patients. Present study is aimed at finding the effect of patient's disease status on the treatment outcome.

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Material & Methods

This cross sectional type of study was conducted in Agra city using the multistage random sampling and a total of 900 patients attending DOTS centers were included in the study. District is divided into eight TUs, out of these five TUs are covering rural areas while 3 are in urban Agra. All the 3 TUs of Agra urban were included in the study and 2 DMCs from each TU were selected randomly. All the Patients registered to all the DOTS centers of the selected DMCs for one year were included in the study up to the desired sample size was complete. Treatment cards of these patients were obtained from their respective DMCs after their outcome had been recorded and all the required information was collected on predesigned pretested schedule. No follow up was done. The information thus collected was analyzed statistically with the help of SPSS software (version 16). Chi square test was used to find out any significant association.

Results

In this observational study 900 patients were studied during treatment and their outcome was observed. It was found that 71.6% of patients had favorable outcome at the end of treatment (45.4% treatment completed and 26.2% cured), 15.1% defaulted, 5.9% died, 2.0% patients failed on treatment while 5.3% were transferred out to other centers. Majority of patients belonged to category-I (42.8%), followed by category III (31.1%), while 26.1% patients were in category II. When outcome of patients

in relation to category of treatment was observed, it was found that 85.7% patients of category III completed the treatment while 72.8% of Category I patients had favorable outcome (32.1% treatment completed and 40.7% cured), while only half of category II patients had favorable outcome with 19.6% treatment completed and 33.6% cured. Almost one fourth patients of category II defaulted (26.4%), while 11.4% & 10.8% of category I and category III patients defaulted. 3.4% patients of category II and 2.3% patients of category I failed on treatment while it was only 0.4% among category III patients. Deaths were also more among category II patients (12.3%). This difference in treatment outcome among patients of different treatment category was found to be statistically highly significant. (Table-1). Regarding type of disease, approximately three fourth (73.8%) patients were found to be having PTB (Pulmonary Tuberculosis), while one fourth (26.2%) were having EPTB (Extra Pulmonary Tuberculosis). On analyzing the effect of type of disease on treatment outcome, it was seen that 83.5% patients of EPTB completed treatment while only 67.4% of PTB patients had favorable outcome (31.9% treatment completion and 35.5% cured). Default was more among patients with PTB (18.2%). No death or treatment failure was observed among EPTB cases. Patients with EPTB had significantly higher rate of favorable outcome (Table-2). It was also observed that 70.7% patients were new, while 0.3% patients were transferred to these centers. Rest 29% patients were

Table 1. Treatment Outcome of Patients Treated Under Various Treatment Categories of DOTS

Outcome	Category I		Category II		Category III		Total No.
	No.	%	No.	%	No.	%	
Treatment Completed	124	32.1	46	19.6	239	85.7	409
Cured	157	40.7	79	33.6	0	0.0	236
Failure	9	2.3	8	3.4	1	0.4	18
Defaulted	44	11.4	62	26.4	30	10.8	136
Died	19	4.9	29	12.3	5	1.8	53
Transferred Out	33	8.5	11	4.7	4	1.4	48
Total	386	42.8	235	26.1	279	31.1	900 (100%)

$\chi^2 = 241.2, df = 5, p < 0.001$

DOTS- Directly Observed Treatment Shortcourse § chi square test was applied between category of patient and various treatment outcome

Table 2. Effect of Type of Disease on Treatment Outcome of Patients Treated Under DOTS

Outcome	Type of disease				Total No.
	Pulmonary		Extra pulmonary		
	No.	%	No.	%	
Treatment Completed	212	31.9	197	83.5	409
Cured	236	35.5	0	0.0	236
Failure	18	2.7	0	0.0	18
Defaulted	121	18.2	15	6.4	136
Died	53	8.0	0	0.0	53
Transferred Out	24	3.6	24	10.2	48
Total	664	73.8	236	26.2	900 (100%)

$\chi^2 = 307.95, df = 10, p < 0.001$

DOTS- Directly Observed Treatment Shortcourse § chi square test was applied between category of patient and various treatment outcome

Table 3. Effect of Various Types of Patients on Treatment Outcome of Patients Treated Under DOTS

Outcome	Type of patients										Total No.
	New/ transfer in		Treatment after default		Failure		Relapse		Others		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.
Treatment Completed	356	55.7	8	7.3	4	8.3	0	0.0	41	42.3	409
Cured	158	24.7	51	46.8	24	50.0	1	14.3	2	2.1	236
Failure	10	1.6	2	1.8	3	6.2	1	14.3	2	2.1	18
Defaulted	56	8.8	31	28.4	9	18.8	3	42.9	37	38.1	136
Died	22	3.4	12	11	7	14.6	2	28.6	10	10.3	53
Transferred Out	37	5.8	5	4.6	1	2.1	0	0.0	5	5.2	48
Total	639	71.0	109	12.1	48	5.3	7	0.8	97	10.8	900 (100%)

$$\chi^{2\#} = 183.7, \text{ df} = 20, \text{ p} < 0.001$$

DOTS- Directly Observed Treatment Shortcourse § chi square test was applied between category of patient and various treatment outcome

Table 4. Effect of Pre-Treatment Sputum Status on Treatment Outcome of Patients Treated Under DOTS

Outcome	Positive		Negative		Not done		Total No.
	No.	%	No.	%	No.	%	
Treatment Completed	16	4.4	180	70.0	213	82.9	409
Cured	236	60.9	0	0.0	0	0.0	236
Failure	12	3.1	6	2.4	0	0.0	18
Defaulted	75	19.4	47	18.3	14	5.4	136
Died	37	9.6	14	5.4	2	0.8	53
Transferred Out	10	2.6	10	3.9	28	10.9	48
Total	386	42.8	257	28.6	257	28.6	900 (100%)

$$\chi^2 = 373.88^*, \text{ df} = 5, \text{ p} < 0.0001$$

DOTS- Directly Observed Treatment Shortcourse § chi square test was applied between category of patient and various treatment outcome

retreatment cases (12.1% treatment after default, 5.3% treatment failure and 0.8% relapse). Regarding the effect of type of patients, it was inferred that new patient had better outcome with 55.7% treatment completion and 24.7% cure rate, while favorable outcome was very less among retreatment cases (54.1% among defaulters, 58.3% among treatment failure and only 14.3% among those who received treatment after relapse of disease). Higher default was observed among those who started treatment after default (28.4%), while 18.8% of failure cases defaulted. Deaths were also more among defaulters and failure cases (11% and 14.6% respectively). Among other patients, only 42.3% completed the treatment, while 38.1% defaulted (Table-3). On analyzing the effect of sputum status, 83% patients, in whom sputum was not present (Extra pulmonary and pediatric cases), completed the treatment as compared to 65.3% and 70% favorable outcome among sputum positive and negative patients respectively. Default rate was almost equal among both sputum positive and negative patients (19.4% and 18.3% respectively) while significantly lower rate of default was observed among patients in whom sputum examination could not be done (5.4%). (Table-4)

Discussion

On analyzing treatment outcome of patients, 71.6% of patients were found to have favorable outcome at end

of treatment (45.4% treatment completed and 26.2% cured), proportion of patients who defaulted, was as high as 15.1%, deaths were 5.9%, 2.0% patients failed on treatment while 5.3% were transferred out to other centers. Bisoi *et al* (5) analyzed and made nearly similar observations i.e. 22.4% while 52.4% patients completed the treatment, 16.4% patients defaulted, failure rate was 4.2% and death rate was 3.1%, while total transferred out cases were 1.4%. Different observations were made by different researchers as Kumar (6) observed somewhat low default rate (10.6%), where as a very high default rate of 22.7% was reported by Masthi NRR (7). Proportion of patients defaulted is more in our study; it may be due to more proportion of category II patients. Death rate was also found to be more which may be due to patient input from tertiary care center, as one DMC in present study is medical college and another one is District Hospital, where proportion of seriously ill patients is more as compared to other centers. According to RNTCP indicators (8), the proportion of patients transferred out should be less than 3%, whereas in our study it is >5%, it may be a way of disguising default.

Among different categories of treatment, favorable outcome was found to be 85.7% among category III, 72.8% among Category I and 53.2% among category II. Almost one fourth patients of category II defaulted



(26.4%). Further 3.4% patients of category II and 2.3% patients of category I failed on treatment. Deaths were also more among category II patients (12.3%) as compare to category I (4.9%) and category III (1.8%). Jaggrajamma *et al* (9) observed that 19%, 38% and 11% of the patients from category I, category II and category III respectively defaulted, while Masthi NRR7 observed a very high rate of default among category I patients (27.78%). A very high rate of default among category II patients in our study may be due to more amounts of drugs, injectable drugs, longer duration of treatment and subsequently more development of side effects. Further patients who have taken treatment previously are more likely to default, and there is natural tendency to treatment interruption among some patients. Higher failure rate among category II was due to the fact that there are more chances of multi drug resistance among those who have taken treatment before. It was also inferred that 83.5% patients of EP tuberculosis completed the treatment while only 67.4% of pulmonary tuberculosis patients had favorable outcome. Patients with pulmonary disease defaulted more (18.2%) as compare to extra pulmonary cases (6.4%). Almost similar observations were made by other researchers (9). The main reason behind good outcome of EP disease is that most of the cases of EP tuberculosis are paucibacillary and most of these patients require lesser medication for shorter duration and none require injectables under DOTS.

In our study, the new patients had better outcome with 55.7% treatment completion and 24.7% cure rate, while retreatment cases had comparatively less favorable outcome (54.1% among defaulters, 58.3% among failure cases and 14.3% among relapse). Almost half of patients (42.9%) who got treatment after relapse defaulted, 14.3% failed on treatment and 28.6% died, while only 3.4% deaths and 8.8% defaulters were found among new patients. 28.4% of treatment after default patients defaulted again, while 18.8% of failure cases defaulted. Deaths among defaulter and failure cases were 11% and 14.6% respectively, while only 3.4% deaths were observed among new patients. Bisoi *et al* (5), observed that among new patients 51.8% completed treatment and 22.3% were cured, the almost similar findings were observed in our study. They observed a default rate of 17.4% among new cases and among relapse, failure and TAD cured patients were 83.3%, 66.7% and 63.6%, while in our study proportion of patients having favorable outcome is very less and further some of these sputum positive retreatment cases are completing treatment but have not been declared cured, indicating that sputum collection and microscopy services are not being provided to all the patients. On analyzing pretreatment sputum status of patients and effect of sputum positivity on treatment

outcome, it was found that 83% patients, in whom sputum was not present, completed the treatment as compared to 65.3% and 70% favorable outcome among sputum positive and negative patients respectively. Default rate was almost equal among both sputum positive and negative patients (19.4% and 18.3% respectively) while significantly lower rate of default was observed among patients in whom sputum could not be done (5.4%). Bisoi S *et al* (5) observed higher default among sputum positive cases (24.7%) as compare to sputum negative patients (13.1%). Lower default among patients in whom sputum cannot be done may be due to large proportion of category I and category III patients in this group, who have to take lesser medicine and for shorter duration.

Conclusion

Poor outcome was observed among category II patients, retreatment cases and also among sputum positive pulmonary cases. Crux of problem in TB control lies in poor compliance of patients, leading to higher default and development of drug resistance. As it was observed that new patients are more compliant as well as more susceptible to treatment. For ensuring compliance DOT providers need to be motivated about educating patients regarding duration and importance of full treatment. Further reasons of treatment interruption need to be explored.

References

1. Global Tuberculosis Control: Surveillance, Planning, Financing. WHO Report 2006, Geneva. World Health Organization, Geneva (WHO/HTM/TB/2006;362:1-2)
2. RNTCP Performance Report, India, second quarter. Central TB Division, Director General of Health Services, Ministry of Health and Family Welfare, New Delhi 2007;1:5-6
3. RNTCP Performance Report, India, first quarter. Central TB Division, Director General of Health Services, Ministry of Health and Family Welfare, New Delhi 2008:4-6.
4. RNTCP Performance Report, India, fourth quarter. Director General of Health Services, Ministry of Health and Family Welfare, New Delhi 2004:3-5
5. Bisoi S, Sarkar A, Mallik S, Haldar A, Haldar D. A study on performance, response and outcome of treatment under RNTCP in a Tuberculosis Unit of Howrah District, West Bengal. *Ind J Commun Med* 2007;32:245-48
6. Kumar M, Singh JV, Srivastava AK, Verma SK. Factors affecting the noncompliance in Directly Observed Short Course Chemotherapy in Lucknow District. *Ind J Commun Med* 2002;27:114-17
7. Masthi NRR, Rajesh JR. A study on The Effectiveness of DOTS on tuberculosis patients treated under RNTCP. *Ind J Public Health* 2006;50:55-57
8. RNTCP at a GLANCE. Central TB division, Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi 2008: 22-26.
9. Jaggarajamma K, Sudha G, Chandrasekaran V, *et al*. Reasons for non compliance among patients treated under Revised National Tuberculosis Control Programme, Tiruvallur district, South India. *Ind J Tuberc* 2007;54:130-35