

Original Research Article

A study on non-compliance in tuberculosis cases towards the directly observed treatment short course under RNTCP in Kanpur Nagar

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ABSTRACT

Background: The goal of Revised National Tuberculosis Control Programme (RNTCP) is to achieve cure rate of at least 85% and to detect at least 70% of the new smear positive cases of tuberculosis (TB). A very high rate of compliance to treatment is required to achieve the target and to prevent the drug resistance. The objective of the study was to study the magnitude and reasons of non-compliance in TB patients towards directly observed treatment short course (DOTS) in Kanpur Nagar.

Methods: Multistage random sampling technique was used to select the study subjects from the two designated microscopy centres (DMC). Information regarding treatment compliance and patient satisfaction was elicited and recorded in the predesigned and pretested questionnaire, analysis was done using SPSS and percentages was used to draw the results.

Results: Out of total 300 study subjects, 41(13.67%) were non-compliant during treatment. Majority of non-compliant study subjects were aged more than 50 years (30.23%), skilled workers (29%), belonged to socioeconomic class III (22.9%), Muslims (19.36%) and educated upto high school (16.33%). The most common cause of non-compliance in the present study was symptomatic relief during treatment (73.20%) followed by intolerance to medications (24.40%).

Conclusions: Compliance to the drug regimen under RNTCP plays a vital role in the cure of the TB cases. Non-Compliance rate being high in the present study, health education of the community at large and regular follow up of all defaulters, to find out the reasons for default and measures to reduce them, requires more emphasis to achieve the goal of RNTCP.

Keywords: Noncompliance, Tuberculosis, RNTCP, DOTS

INTRODUCTION

Tuberculosis (TB) is one of the most ancient infectious diseases caused by *Mycobacterium tuberculosis*.¹ The population most commonly affected is the young and economically productive one. It is a worldwide public health problem despite the fact that the causative organism was discovered more than 100 years ago and

highly effective vaccines and drugs are available making TB a preventable and curable disease. Poor adherence to antitubercular medication i.e. non-compliance is a major barrier to its global control.

The South East Asia region carries the highest burden of tuberculosis amongst all World Health Organization (WHO) regions. In 1993, WHO declared it as a global emergency.² India is one of the most populous countries

in the world, contributing the major share of TB cases in the world and accounts for one third of the global burden of TB. Worldwide, in 2014, 9.6 million people are estimated to have fallen ill with TB and 6 million new cases (63%) of TB were reported to WHO. In 2014, TB killed 1.5 million people (1.1 million HIV-negative and 0.4 million HIV-positive).³

National Tuberculosis Control Programme in India was started in 1962 with significant epidemiological impacts. In 1997, Revised National Tuberculosis Control Program (RNTCP) was launched as a national programme in phased manner. Directly Observed Treatment Short course (DOTS) is a comprehensive strategy for TB control, and is the only strategy which has proved to be effective in controlling TB on a mass scale. DOTS ensure that a patient takes medicine regularly until he is cured.

Kanpur is one of the greatest industrial giant of Northern India, where life runs in its full spectrum of riches and rags and aptly known as Manchester of India.⁴ Pollution is very high in this city affecting adversely the health of its population particularly exposing them to chronic respiratory diseases. RNTCP status report 2010, states that Kanpur District covers maximum population under RNTCP (45 lakhs) in Uttar Pradesh during the time period of 4th quarter 2008 to 3rd quarter 2009.⁵ Therefore, more and more operational researches in RNTCP are needed at this juncture to know whether it is heading towards the right direction as far as pace and qualities of implementation of the programme are concerned. Keeping this in view, the present study was conducted.

METHODS

Kanpur Nagar district has a population of 45.73 lakhs (Census 2011).⁶ The district has been divided into nine Tuberculosis Units (TU) for implementing RNTCP. Each

TU covers four to five microscopic centres known as Designated Microscopic Centre (DMC) and there are in total 37 DMCs working under nine TUs. Each microscopic centre is assigned a population of one lakh and caters to all DOTS centres falling under its jurisdiction. Each TU caters a population of 5 lakhs.

Multistage simple random sampling technique was used to select the study subjects in the present study. In the first stage of sampling, two TUs were selected from the list of nine TUs using simple random sampling without replacement technique. Similarly, in the second stage of sampling, one DMC was selected each from the two identified TUs, using simple random sampling technique. All the patients who were registered in the selected DMCs in the last two quarters of the year 2011 (July to December 2011) were taken into consideration for the present study. A total of 300 patients were registered, which formed the study population. They were interviewed personally and also the treatment cards of patients were obtained from their respective DMCs to confirm the data elicited from the patients.

Information on patient's literacy, occupation and personal habits like smoking and drinking was collected and entered in predesigned and pretested questionnaire. Patients who defaulted on treatment were further traced in the community and interviewed thoroughly regarding reasons of default. The collected data was analysed using SPSS, percentages and chi square test were applied and conclusions were drawn accordingly.

RESULTS

Among all study subjects, cure rate was 61.00% and subjects who completed treatment were 19.66%. Failure, default and death rates were 3.67%, 13.67 and 1.67% respectively (Table 1).

Table 1: Distribution of study subjects according to treatment outcome.

Outcome	N (%) (N=300)	Expected outcome RNTCP (%)
Cured	183 (61.00)	85.00
Treatment completed	59 (19.66)	3.00
Failure	11 (3.67)	<4.00
Defaulted	41 (13.67)	<5
Died	3 (1.00)	<4
Transferred out	3 (1.00)	
Total	300	

Maximum (30.23%) non-compliant study subjects were in the age group greater than 50 years, while there were no non-compliant study subjects in the age group less than 10 years (Table 2). Among Hindu and Muslim study subjects, non-complaints were 13.11% and 19.35% respectively (Table 2). Among skilled workers, there were more non-compliant study subjects (29.03%) while

there were no non-compliant study subjects in professionals.

According to modified B. G. Prasad social classification, social class III had maximum (22.92%) non-compliant study subjects (Table 2).⁷ New cases category (category I) had more non-compliant study subjects (14.64%) as compared to retreatment cases (Category II, 9.83%, Table

3). Among the non-compliant study subjects who missed the doses, maximum (73.20%) were those who missed the doses as they were symptomatically relieved followed

by those who could not tolerate the medicines (24.40%) followed by those whose symptoms were not relieved by medicines (2.40%).

Table 2: Bio social profile of non-compliant study subjects.

Variables		Total study subjects (N=300)	Non-compliant study subjects (n=41)	
			No.	%
Age in years	<10	8	0	0.00
	10-20	44	6	13.63
	21-30	72	9	12.50
	31-40	86	7	8.14
	41-50	47	6	12.76
	>50	43	13	30.23
Religion	Hindu	267	35	13.11
	Muslim	31	6	19.35
	Others	2	0	0.00
Education	Illiterate	51	7	13.72
	Primary school	48	4	8.33
	Middle school	41	6	14.63
	High school	49	8	16.33
	Higher secondary	66	10	15.15
	Graduate	36	5	13.88
	Post graduate	9	1	11.11
Social class	Class I	0	0	0.00
	Class II	3	0	0.00
	Class III	48	11	22.92
	Class IV	162	20	12.35
	Class V	87	10	11.49
	Total	300	41	13.67

*According to modified B. G. Prasad social classification.⁶

Table 3: Non-compliant study subjects according to category of treatment.

Category	Total study subjects (N=300)	Non-compliant study subjects	
		No.	%
New cases (Category I and Category III)	239	35	14.64
Retreatment cases (Category II)	61	6	9.83
Total	300	41	13.67

DISCUSSION

India is one of the most populous countries in the world, contributing the major share of TB cases with TB incidence rate 167 per 1 lakh population, case detection rates 74%, mortality rate of 17 per 1 lakh population (2014) and accounts for one third of the global burden of TB.⁸ A single patient can infect 10 or more people in a year, leading to rapid spread of disease.

In the existing literature, non-compliance is defined as one or more of the following: (1) missing >2 consecutive weeks of DOTS; or (2) prolongation of treatment >30 days due to sporadic missed doses; or (3) poor outcome of therapy, defined as a microbiologic or clinical failure of initial therapy resulting in morbidity, relapse, or

death owing to TB in defaulters (who miss two consecutive months of DOTS).⁹

In our study, treatment success rate (cured and treatment completed combined) was 80.67% against expected rate of 85.00% cured and 3.00% treatment completed.

We found default rate of 13.67% overall, higher in pulmonary cases (15.70%) and more common in males. A study from South Africa also had reported that treatment interruption was more in men.¹⁰ Our findings are almost similar to those of other studies carried out in India, especially from Uttar Pradesh. In a study by Mittal et al in Agra, Uttar Pradesh, default rate was observed to be 15.10% and in study of Mahesh et al in Lucknow, default rate was reported to be 10.60%.^{11,12} As per RNTCP guidelines, default rate must be less than 5.00%.

Our most of the study subjects belong to 30-50 years age group. Similar results were observed in various studies indicating that more of the economically productive age group (20-50 years) is suffering from TB.^{12,13} In our study, we observed that default rate (30.23%) as well as failure rate (13.95%) was maximum in age group more than 40 years. These could be attributed to the self-neglect. Most of the defaulters reported that the patient was the only economically active person in the family and hence, could not spare time to visit DOTS clinic on a regular basis.

In the present study, maximum (22.00%) of the study subjects were educated upto intermediate followed by illiterate (17.00%). Similar results were observed in other studies where maximum defaulters belonged to illiterate group. Therefore, health education forms important tool to improve compliance. Health education has major effect on non-compliance. Various studies have revealed that the compliance of DOTS was significantly high among those who have good knowledge about various aspects of disease. The innovative strategies in health education, therefore, are the need of the hour.¹⁴

In our study, 79.70% patients belonged to the category of new cases (old Cat. I and Cat III combined) followed by 20.30% in Category of retreatment cases. So it's assumed that the proportion of retreatment cases would be high to start with but would gradually decrease with improvement of patient compliance and cure rate.

The most common reason for default observed, was relief of symptoms by medications (73.20%), followed by intolerance to anti tubercular drugs (24.40%) and symptoms not relieved by medicines (2.40%). Other common reasons for default includes unsuitability of opening time of the DOTS centre, lack of proper education, long distance to travel, noncontact with the health worker on scheduled time, non-cooperative behaviour of health staff. Jaiswal et al in their study found that the reasons for default includes that the patient needs were not met by the health system included convenient clinic timings, inability of the staff to deal with drug side-effects and patient conception of equating well-being with cure.¹⁵

The present study also has certain limitations. We studied only two DMCs out of total 37 DMCs of Kanpur nagar, so the factors operating at some DMCs and affecting DOTS strategy may not have been brought out. Responses of the study subjects during the interview might not have been accurate due to recall bias. The reasons for default were not elicited from patients, who had migrated.

In order to improve compliance, we should follow all the defaulters to find out the reasons for default and implement measures to correct the same. This is essential as they constitute pool of infectors in the community and

also add to the problem of multi drug resistant TB (MDR-TB) requiring more prolong and expensive therapy.

We should promote awareness of masses about TB as curable disease and high quality free of cost treatment facilities available (DOTS centres) in nearby areas. We can seek co-operation of private practitioners, NGOs and corporate sector. Economic support to the patients on DOTS belonging to lower socio-economic till the completion of treatment may be considered.

As it has been noticed in various studies, as mentioned above, that young male population is more susceptible, brings out the need to evolve gender specific motivation strategies to minimize default. Health education of community of large, with a view to promote community awareness, community co-operation & community participation in TB control is mainstay to decrease default.

DOTS provider being the key person in the DOTS strategy, be trained adequately about the signs and symptoms of TB, managing side effects of the drugs under DOTS, preventive measures of the disease, proper filling of the treatment card, regular advice for continuing the treatment, motivation of the patients towards DOTS, follow-up of the sputum examination. Care should be taken to provide DOTS as per patient's convenience through community.

DOT providers, may reduce the treatment default. Periodic monitoring of the community DOT providers by the health staff is important to minimize default.

CONCLUSION

In order to decrease default rate and achieve RNTCP goals steps like health education, community awareness along with periodic monitoring of adequately trained DOTS provider should be considered.

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